

## **Industry-leading service provider of viral challenge studies**

Annual Report and Financial Statements 2018

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## Our vision:

to become the partner of choice for companies developing products in airways diseases.

## Our mission:

building a profitable clinical development services business supporting product development for our clients through human challenge studies to establish early proof-of-concept.

## Financial highlights

Revenue and Other Income

**£13.6m**

**+10.5%**

(2017: £12.3 million)

Adjusted loss before tax<sup>1</sup>

**£9.6m**

**-27.6%**

(2017: £13.2 million)

Cash and cash equivalents

**£13.4m**

as at 31 December 2018

Research and development expense

**£4.8m**

**-21.0%**

(2017: £6.1 million)

## Operational highlights

- Increased demand for services translating to a strong base of revenue already contracted for 2019. Operational improvements will bring costs into line with service revenue, supporting business turnaround and enabling future growth and cash generation
- Good progress on business turnaround with refocused services business model and R&D expenses significantly reduced to focus specifically on opportunities to support the enhancement of development services such as new virus manufacturing or biomarker opportunities
- Pipeline of opportunities for 2020 looking exceptionally strong
- Rationalised business focus onto services business with the closing of certain areas of the business that were not viable
- Assets progressing within Imutex Limited (joint venture) – FLU-v, AGS-v

1. Adjusted loss before tax excludes costs relating to the impairment of intangibles, provision against virus inventory and share of loss from associates and joint ventures: (1) PrEP Biopharm Limited consolidated balance sheet value of £4.7 million impaired to £nil as at 31 December 2018; (2) consolidated balance sheet value of intangible assets of £2.6 million impaired to £nil as at 31 December 2018; and (3) provision of £1.2 million made against certain virus stock with consolidated balance sheet value of £1.2 million.

## At a glance

**An industry leading clinical development services business pioneering human disease models based upon viral and allergen challenge and leading the way in the use of human challenge studies to establish early proof-of-concept.**

### About hVIVO

Established in 1989 as a spin out from Queen Mary University, London, hVIVO is a trusted partner and industry-leading clinical development services business pioneering human disease models based upon viral challenge. Using human challenge studies to establish early proof-of-concept, hVIVO's clinical trial platform can accelerate drug and vaccine development in respiratory and infectious diseases, specifically leveraging hVIVO's established human

disease challenge models in influenza ("flu"), respiratory syncytial virus ("RSV") and human rhinovirus ("HRV") and more recently the expansion and development of these models in other respiratory indications for asthma, chronic obstructive pulmonary disease ("COPD"), cough and related new therapies and in special populations.

[www.hvivo.com](http://www.hvivo.com)

## Our services



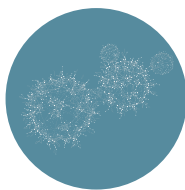
**Human  
challenge  
full-service  
solution**

**Industry leading  
provider of viral  
challenge studies**

**Disease  
models**

**Laboratory  
services**

## hVIVO models



**Infectious  
diseases**



**Respiratory**



**Laboratory  
offering**

FLU

HRV

RSV

Asthma

Cough

COPD

Virology

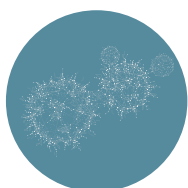
Immunology

Biomarkers

## Our services continued

We continue to satisfy the needs of our customers through a commitment to quality and exceptional service. We apply the experience and know-how accumulated from over 50 challenge studies to ensure effective study design and service delivery.

The Company conducts studies and provides services for customers, both pharmaceutical and biotech companies, utilising a range of different clinical trial and laboratory methodologies across differing viral challenges.



### Infectious diseases

hVIVO conducts human challenge studies in order to support the efficient and effective development of new-generation vaccines and treatments for infections including flu, HRV and RSV.

New approaches outside of large-scale field trials can be considered to provide early evidence of proof-of-principle in humans. Our viral challenge services and facilities provides the means for clients to gain a faster less expensive route to understanding the efficacy of their products.

#### Influenza ("flu") vaccines and treatments

##### Proven flu challenge models

hVIVO has been studying influenza for over 20 years and been conducting influenza human challenge studies with our flu disease models for more than 15 years.

We have conducted numerous flu challenge studies for a range of industry, governmental and academic customers, making our models the most well-used commercial flu disease models available on the market.

Flu vaccines

Antivirals and treatments

Immunomodulators

#### Respiratory syncytial virus ("RSV") vaccine and treatments

##### Proven RSV challenge models

We remain the only company to have a validated RSV challenge model commercially available to customers.

Vaccines

Antivirals and treatments

Immunomodulators



### Respiratory disease

We believe the challenge model is not only helpful as a proof-of-concept for the effectiveness of agents directed at the viruses, but also as proof-of-mechanism for novel products in diseases where respiratory viruses are known to induce exacerbations. hVIVO is expanding its offering into airways diseases such as asthma, cough and COPD and these expanded services offerings have the potential to provide the Company with valuable additional revenue streams.

#### Asthma and chronic obstructive pulmonary disease ("COPD")

We have created a viral model using HRV to induce exacerbations.

#### Acute cough

We have now completed a novel model using HRV to stimulate cough.



## Laboratory services

Consolidating biomarker analysis to a single source lab reduces time and costs throughout development programmes.

Innovative assays can speed up the testing process considerably, supporting swift market delivery of customer products.

### Service offering

Reliable laboratory analysis underpinned by scientific expertise is essential when processing and analysing clinical samples. Robust quality processes support our team of scientists in the delivery of submission-ready data.

Virology

Immunology

Biomarkers

## Human challenge full service solution

**Unparalleled experience in the design, conduct and analysis of human models of disease**

Study design and protocol development

Recruitment

Monitoring

Ethics and regulatory submission

Pharmacy

Data management and biostatistics

Laboratory support

Biomarker development

Clinical study report

Clinical trial: inpatient or outpatient

### Standardised study process

#### Committed to delivering study excellence



#### Protocol design

- Study management process
- Services deliver quality results
- Meeting customer needs and timelines
- Trials conducted using controlled settings and processes



#### Screening and recruitment

- Recruitment of volunteers in the UK using the 'FluCamp' brand



#### Quarantine

- Bespoke quarantine unit in Whitechapel, London for conducting challenge studies; 24 en-suite rooms



#### Viral challenge

- Well characterised virus
- Exact exposure time to virus



#### Intensive sample collections

- Virology
- Immunology
- Biomarkers



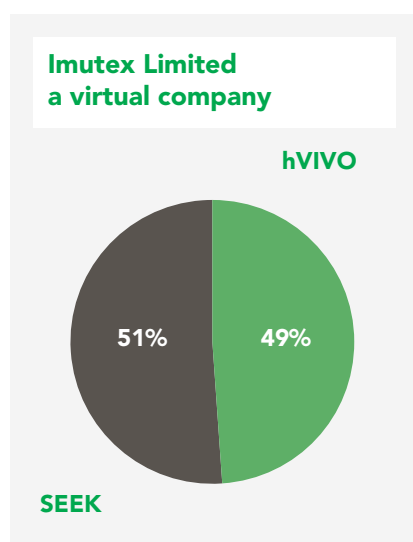
#### Quarantine discharge and follow up

- Immunogenicity
- Seroconversion
- Standard 28 days can be up to one year

# Imutex Ltd – joint venture

## Overview

In April 2016, hVIVO formed Imutex Limited ("Imutex") with the SEEK Group ("SEEK") as part of a co-development using hVIVO's services in return for an opportunity to benefit from future potential upside of the assets. hVIVO's 49% owned joint venture with SEEK is developing two novel vaccine candidates, FLU-v and AGS-v.



### About FLU-v – a Phase III enabled, broad spectrum stand-alone, universal influenza vaccine candidate

FLU-v is a novel first-in-class 'universal', broad spectrum, stand-alone, influenza vaccine candidate. FLU-v is designed to provide broad-spectrum cover against multiple influenza strains and does not require annual immunisation alongside an annual influenza vaccine to confer immunity. It is also designed to minimise the impact of the influenza virus by reducing symptoms, potentially relegating influenza to a much milder disease by stimulating an immune response mediated through T-cells and B-cells that recognise infected cells and destroy them, in contrast to seasonal influenza vaccines that prevent infection through antibody protection against external proteins.

Two Phase IIb studies have achieved primary endpoints:

- field study, FLU-v 003; and
- challenge study, FLU-v 004.

### About AGS-v – a universal mosquito-borne diseases vaccine candidate

AGS-v is a mosquito-borne disease vaccine with a novel proposed dual action mechanism of preventing infection in humans whilst controlling the mosquito population. AGS-v is composed of four salivary peptides isolated from *Anopheles gambiae* salivary glands, but that are common across a number of mosquitoes.

In 2018 the NIH presented partial results from the Phase I first-in-man study of AGS-v completed by the NIH. Based upon currently available data the Phase I study met primary objective endpoints with regard to safety and humoral response. The remaining endpoints will be evaluated once the full and final data are available in due course, at which point a full assessment of the trial results will be possible when the NIH completes the sample analyses.

We continue to endeavour to progress strategic discussions with regards to the assets in our joint venture, Imutex, and to maximise the strategic options available to both companies.

Imutex current pipeline					
Candidate	Phase				Status
	Pre-clinical	I	II	III	
<b>FLU-v</b> Influenza					<ul style="list-style-type: none"> <li>• Safety and immunogenicity endpoints met in Phase IIb field study (UNISEC consortium in the EU) and efficacy endpoints met in a challenge study in collaboration with NIAID/NIH in the US</li> <li>• Ready for Phase III in Europe and US</li> </ul>
<b>AGS-v</b> Mosquito-borne diseases					<ul style="list-style-type: none"> <li>• Phase Ib study completed by NIH – preliminary results positive, complete results expected in 2019</li> </ul>



# Investment proposition

## Uniquely positioned clinical development services business in airways diseases.

### Revenue-generating business providing value-added drug development services in airways diseases

- Strong fee-for-service pipeline
- Broad range of customers, from large pharma to small biotech

### Unique market opportunity in human challenge studies with further opportunities to expand services and increase revenues

### Targeting the creation of significant shareholder value through substantial growth and achieving sustainable profitability

- Focussed on operational excellence and building scale
- Leading the way in new challenge model development

### Aiming to rebuild the business and return to £100m+ market capitalisation

## Industry leader and trusted partner

Over 15 years' experience conducting and analysing human models of disease:

- challenging both healthy volunteers and patients with flu, RSV or HRV;
- extensive experience in virology; and
- experts in virus production, viral challenge and host response related to virus insult.

Established a strong reputation for expertise in providing disease insights and technical execution:

- with over 100 publications in peer reviewed journals demonstrating extensive experience in virology;
- that enable early indications of efficacy of new products in disease models; and
- that identify key biological traits of patients who respond to a novel therapy.



# Executive Chairman's statement



The Board of hVIVO is pleased to report a year of progress and a period of steady revenue growth.

**Dr Trevor Philips**  
Executive Chairman

## Introduction

The Board of hVIVO is pleased to report a year of progress and a period of steady revenue and other income growth. However, it has also been a year of transition for the Company. The management changes announced in the second quarter provided the opportunity to review and confirm a refocused business model centred on the provision of human challenge study services and to reset strategic priorities. As part of this review, we undertook measures to ensure the business is better placed to operate efficiently, enabling revenue growth and facilitating the transition of the Company into a cash-generating position in the medium term. We have reduced R&D expenses significantly, focussing any future spend specifically on opportunities to support the enhancement of our development services such as new virus manufacturing or biomarker opportunities. There have been multiple challenges to overcome with regard to our business operations during this transition. While the changes instituted across the business in 2018 and into 2019 will result in some cost savings being recognised in both years, the effect will be fully realised from 2020.

## Human challenge studies

### Market opportunity in infectious diseases

Human challenge studies are an increasingly accepted approach for obtaining initial clinical proof-of-concept for novel drug and vaccine candidates, especially in the context of tackling viral disease and the need to obtain early indications of efficacy prior to embarking on costly field-based clinical trials.

The potential benefits of human challenge models include:

- early human proof-of-concept efficacy data to support drug and vaccine candidate selection;
- accelerated development of pipeline compounds, through early identification of the appropriate endpoints, biomarkers and patient populations for incorporation in later clinical studies; and
- reduced costs as the model requires a relatively small number of subjects investigated over a shorter period of time.

**We remain focussed on building a profitable clinical development services business. This will be delivered through a strategy of driving revenue growth and reducing operating costs to enable cash generation.**

hVIVO has particular expertise in conducting human challenge studies using influenza ("flu"), human rhinovirus ("HRV") and respiratory syncytial virus ("RSV") for pharmaceutical and biotech companies.

We have been conducting viral challenge studies for over 15 years, initially using cold and flu viruses and more recently adding RSV. We remain the only company to have a validated RSV challenge model commercially available to customers.

### **Human challenge studies and their potential in respiratory disease**

We believe the challenge model is not only helpful as a proof-of-concept for the effectiveness of agents directed at viruses, but also as proof-of-mechanism for novel products in diseases where respiratory viruses are known to induce exacerbations. hVIVO is expanding its offering into airways diseases such as asthma, cough and COPD, and these expanded service offerings have the potential to provide the Company with valuable additional revenue streams.

We are encouraged by the high level of ongoing contract discussions in which we are engaged in this area, which we hope in the medium and longer term will strengthen the Company's backlog of service contracts leading to sustainable revenue streams.

### **Operational review**

#### **Progress across contracted pipeline and new business**

##### **Human challenge studies**

We continue to satisfy the needs of our customers through a commitment to quality and exceptional service. We apply the experience and know-how accumulated from over 50 challenge studies to ensure effective study design and service delivery for our customers.

The Company has conducted studies and provided services for customers, both pharmaceutical and biotech companies, utilising a range of different clinical trial and laboratory methodologies across differing viral challenges. The diversification of the range of services, built on the Company's industry-leading experience in viral challenge studies, has led to increasing revenue and client demand. We have re-aligned our sales and marketing activities to our refocussed business services offering and as a result, our contracted backlog for 2019 remains strong and is showing a substantial increase on 2018, with the pipeline of opportunities for 2020 also looking exceptionally strong.

With the unit operating at 40% bed occupancy during 2018 there is plenty of scope for increased utilisation to fulfil the demand in 2019 and beyond to support revenue growth targets.

# Executive Chairman's statement *continued*

## **Operational review** *continued*

### **Completion of a novel cough model study using human rhinovirus ("HRV")**

The Company successfully completed a study of a potential new medicine for the treatment of cough for a large pharmaceutical company customer. This was the first time that hVIVO has conducted a study using HRV to stimulate cough and, as the model is now validated, this represents a new service offering for customers.

### **Completion of US Government agency collaboration – Defense Advanced Research Projects Agency ("DARPA")**

A flu contagiousness project conducted with a cost-sharing grant from DARPA, via its Prometheus programme was completed on time at the end of 2018 and the results of the analytics work have now been delivered to DARPA. The costs associated with this project are reported as R&D expense and the grant funds as other income.

### **Driving operational excellence, reducing our cost base to support turnaround of the business and enabling future growth and cash generation**

The Company has taken multiple steps to reduce its cost base and inefficient legacy business processes to meet the needs of its refocused business model of fee-for-service challenge study services. The reductions have focussed on headcount savings alongside numerous process-driven efficiencies, as well as ceasing the Company's non-core activities, including discontinuing discovery activities. The redundancy consultation process for our discovery group is now complete and the scientific research facility in Welwyn, UK has been closed, rationalising the operations of the Company to its main site in London reducing our R&D expenses significantly. Any future R&D expense will focus specifically on opportunities to support the enhancement of our development services such as new virus manufacturing or biomarker opportunities. These savings will be fully recognised across 2019 and 2020.

Another focus of the turnaround has been a restructuring to improve the effectiveness of our unit and recruitment operations. We have reduced dependence on expensive consulting and interim staff that historically have been used to support service levels required to meet study demand. In addition, we have restricted expenditures in areas that are not core to the business strategy. These changes are forecast to produce total cost savings of £3.9 million across 2018, 2019 and 2020. The next phase is to introduce further process efficiencies that will realise an additional operating cost saving of a similar order of magnitude and enable us to manage a significantly higher workload without a concomitant increase in our cost base. While we recognise that the changes implemented in 2018 and 2019 will only be fully realised from 2020, we believe that the Company will be in a much stronger position, with potential to be cash generative, as long as we achieve the anticipated level of revenue.

## **Alliances/joint ventures**

Imutex Limited ("Imutex"), hVIVO's 49% owned joint venture with SEEK Group ("SEEK"), is developing two novel vaccine candidates, FLU-v and AGS-v. FLU-v is a first-in-class 'universal', broad spectrum, stand-alone, flu vaccine candidate which is supported by a compelling data package.

AGS-v is a mosquito-borne disease vaccine with a novel proposed dual action mechanism of preventing infection in humans whilst controlling the mosquito population.

### **FLU-v – completion of a compelling Phase II FLU-v data package around this first-in-class 'universal', broad spectrum, stand-alone, influenza vaccine candidate**

- Positive results from the Phase IIb field (FLU-v 003) and challenge Studies (FLU-v 004) were announced in the first half of 2018
- Post period; reported update that the Phase IIb challenge study for FLU-v (FLU-v004) achieved the primary endpoint of a statistically significant reduction in Mild to Moderate Influenza following additional analysis of the samples from the study by the NIAID
- Continue to expect publication of the data from these UNISEC (FLU-v 003) and NIAID (FLU-v 004) FLU-v studies in peer reviewed journals in due course

The successful achievement of statistical significance in the primary endpoints from two Phase IIb studies confirms that FLU-v has clinical impact in establishing immunity and disease, symptom and viral load reduction. The exploratory design of FLU-v-004 has also enabled us to determine what we believe to be the most appropriate clinical efficacy endpoint, relating to confirmed influenza infection, for application in the Phase III programme following discussion with the regulatory authorities. We are currently in the process of setting up those regulatory meetings.

#### AGS-v – universal mosquito-borne diseases vaccine candidate

- NIH presented partial results from the Phase I first-in-man study of AGS-v
- Based upon currently available data the Phase I study met its primary objectives and endpoints with regard to safety and humoral response
- Remaining endpoints will be evaluated once the full and final data are available in due course
- Full assessment of the trial results will be possible when the NIH completes the sample analyses

We continue to make progress regarding strategic discussions related to the assets in our joint venture, Imutex, helping to maximise the strategic options available to both companies. We have had a number of positive discussions and we are continuing to explore a number of options to enable the continued development of the FLU-v vaccine.

#### PrEP Biopharm Limited

##### PrEP-001 – novel pan-viral prophylactic

- Management performed an impairment assessment and determined that a full impairment of the carrying amount of the investment in PrEP Biopharm Limited is required due to consideration of the economic performance of this asset. The consolidated balance sheet value of our investment in PrEP Biopharm Limited of £4.7 million was impaired to £nil as at 31 December 2018
- The impairment of PrEP Biopharm is not an indication of an opinion on the utility of the PrEP-001 asset, it is a reflection of the fact that further development will need investment and this is no longer part of the Company's refocused business model

#### Board changes

Kym Denny, Chief Executive Officer, Graham Yeatman, Chief Financial and Business Officer and Jaime Ellertson, Non-Executive Director, as previously announced, all stepped down from the Board and left the Company.

#### Management changes

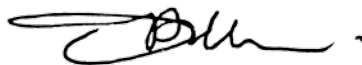
In 2018 we were pleased to appoint Tim Sharpington as Chief Operations Officer, and Shelley Fraser as Finance Director and Company Secretary effective from January 2019.

#### Summary and outlook

We remain focussed on building a profitable clinical development services business targeting the establishment of early proof-of-concept for customers through the execution of human or viral challenge studies. This will be delivered through a strategy of driving revenue growth and reducing operating costs to enable cash generation. With the R&D expense reducing significantly in 2019, the R&D guidance range for 2019 is £1 million to £1.5 million.

The business remains extremely busy with a good level of unit occupancy and significant resource directed to achieving operating efficiencies. Our contracted backlog for 2019 remains strong and is showing a substantial increase on 2018 with the pipeline of opportunities for 2020 also looking exceptionally strong. With our continued focus on maximising the potential of our services business, coupled with a focus on operational efficiency and encouraging new business demand, we are confident of hVIVO's ability to deliver its targets.

The year was about turning around the business, addressing inefficiencies and focussing. We have achieved a lot and in 2019 we are starting to see the benefit of the changes. However, the route to profitability requires more adjustments to the business and we are in the process of making additional changes and adjustments to the business operations as we target profitability in 2020.



**Dr Trevor Phillips**

Executive Chairman

11 April 2019

# Refocussed business model and strategy

Following the management changes in 2018, the Company has focussed on its core clinical development services business, in turn striving to become a cash-generative company.

## Our business model

### Inputs

#### People

hVIVO has 138 employees with expertise in virology, immunology, infectious diseases, respiratory and biomarker science

#### Partners

Well-established relationships with large pharma, biotech, US government agencies and academia

#### Know-how and proprietary models

Pioneer of human disease models based upon viral and allergen challenge with hVIVO's established clinical trial platform for product and vaccine development in respiratory and infectious diseases

#### Quality results

hVIVO is an industry leader and trusted partner with a strong reputation for delivery, customer focus and expert input

### How we create value

#### Core clinical development services

- Focus on fee-for-service offerings

#### Improving operating efficiency

- Reducing costs
- Enabling rapid delivery of data to clients
- Focussed upon quality and service delivery

#### Leveraging know-how

- Expanded service offerings
- Leveraging know-how and models to establish longer term, higher value contracts
- Operating as a true development partner, not just a service provider

The strategy is being enabled through execution of a refocussed business model.

## Our strategic priorities

### Outcomes

Targeting the creation of significant shareholder value through growth and achieving sustained profitability

- 1 Driving revenue growth**
  - Cash generation
  - Sustained profitability
- 2 Operational excellence**
  - Reducing costs
  - Enabling rapid delivery of data to customers
  - Focussed upon quality and service
- 3 Cost control**
  - Reducing costs/expenditure
- 4 Adoption of expanded services**
  - Developing new challenge models
  - Engaging with customers to support market adoption
- 5 Maximise strategic options available to the Company and its joint venture, Imutex**
  - Evaluating options to support value creation

Underpinned by our culture and values



One team

Integrity

Growth

Innovation



# Market opportunity

## Human challenge studies

With the evolution of increasingly more virulent viral diseases, increasing complexity of managing chronic diseases and growing pressure to deliver safer, more effective treatments the delivery of clinical trials needs to continuously evolve in order to ensure product development remains effective and efficient. Human challenge studies are an increasingly accepted approach for obtaining initial clinical proof-of-concept for novel drug and vaccine candidates, especially in the context of tackling viral disease and the need to obtain early indications of efficacy prior to embarking on costly field-based clinical trials.



### The potential benefits of human challenge models include:

- Early proof-of-concept efficacy data to support drug and vaccine candidate selection
- Accelerated development of pipeline compounds, through early identification of the appropriate endpoints, biomarkers and patient populations for incorporation in later clinical studies
- Reduced costs as the model requires a relatively small numbers of subjects investigated over a shorter period of time

### Addressable market is large and growing

The global Phase I-IV CRO market is forecast to grow at an average annual growth rate of 6.8% from 2016 reaching approximately \$44 billion in 2021, with Phase II studies accounting for over 26% of this market

Source: 2017 CRO Market Size Projections 2016-2021 by ISR reports.



## Our KPIs

We measure our performance against a number of KPI targets as set out below.

### Financial

#### Revenue and other income

# £13.6m

2017: £12.3m

**Description:** Increased 10.5% to £13.6 million reflecting the growing demand for our services during 2018, particularly our industry-leading RSV human challenge model.

#### Strategic alignment

1 4

#### Adjusted loss before tax

# £9.6m

2017: £13.2m

**Description:** Narrowed 27.6% to £9.6 million due to ongoing operational efficiency and cost containment.

Adjustments: impairments, provision against virus inventory and share of loss from associates and joint ventures.

#### Strategic alignment

1 2 3 4

#### Net new business

# £21.0m

2017: £16.6m

**Description:** Increased 26.7% to £21.0 million reflecting adoption of the Company's services. Net new business consists of contracts and binding commitments won in the year less cancellations of previous signed contracts.

#### Strategic alignment

1 4

### Operational

#### Backlog

# £15.8m

2017: £8.0m

**Description:** Increased 97.0% to £15.8 million due to the increase in awarded net new business, positioning hVIVO to deliver revenue growth in 2019 and beyond. Backlog represents future services revenues from work not yet completed or performed under contracts and pre-contract binding commitments.

#### Strategic alignment

1 4

#### Volunteers

# 233

2017: 218

**Description:** Volunteer numbers increased by 6.9% to 233, reflecting the increased client demand for challenge model services.

#### Strategic alignment

1 2 3 4

#### Utilisation of unit

# 40%

2017: 35%

**Description:** Increased from 35% to 40% due to the increasing number of volunteers, enabling better absorption of the fixed-cost base.

#### Strategic alignment

1 2 3 4

### Our strategic priorities

1 Driving revenue growth 2 Operational excellence 3 Cost control 4 Adoption of expanded services

# Financial review

## The Company remains focussed on controlling costs and generating cash with the drive to be sustainably profitable.

The Group has driven cost efficiencies, reviewed the return on its investments and prioritised its focus on building a strong pipeline of revenue generating challenge studies. Our financial performance reflected growth in revenue and other income, and a reduction in adjusted loss before taxation against the prior year, narrowing the gap towards achieving future profitability. Our loss before tax increased to £18.9 million (2017: £14.8 million). During 2018, management reviewed investments and aligned assets to the future growth strategy of the business resulting in certain impairment charges and the rationalisation of premises and non-essential systems.

The Company remains focussed on controlling costs and generating cash with the drive to be sustainably profitable. The current cost reduction programmes are forecasted to deliver improvements totalling £3.9 million across 2018, 2019 and 2020 and will complete the first stage. The next phase of process efficiencies is expected to realise an additional operating cost saving per year of similar magnitude to the annual impact of the cost savings and will enable us to manage a significantly increased workload without a concomitant increase in our cost base.

### Income statement

Revenue £11.0 million (2017: £10.9 million) and other income £2.6 million (2017: £1.5 million) for the year ended 31 December 2018 totalled £13.6 million (2017: £12.4 million), generated from client challenge studies compared to 2017, where revenue included £2.9 million from our equity investment (comprised primarily of £2.6 million from the FLU-v Phase IIb clinical study). In both years, other income has been achieved from a cost-share grant with DARPA of £2.3 million (2017: £1.3 million), representing overall growth of 10.5%.

Adjusted loss before taxation was £9.6 million (2017: £13.2 million) – with adjustments being made for exceptional items from the impairment of legacy investments and provision of virus stock manufacture for conducting client studies. Cost synergies achieved through process improvements, rationalisation of premises and headcount reductions have driven the contraction of the loss versus prior years.

Research and development ("R&D") expense was down to £4.8 million (2017: £6.1 million) as a result of the termination of the majority of hVIVO's discovery projects. The majority of this year's R&D spend was applied to manufacturing virus stock to support the Company's clinical development services offering and on the completion of the flu contagiousness project with DARPA. The R&D spend will reduce even more significantly in 2019 as the full benefits of changes made this year are fully recognised; the R&D spend in the future will only be to support the Company's service offerings such as virus manufacture or biomarker opportunities.

Share of loss of associates and joint ventures was £0.7 million (2017: £1.6 million), reflecting the share of loss from hVIVO's investments in PrEP Biopharm Limited and Imutex Limited. A further impairment of £4.7 million on PrEP BioPharm Limited was recognised as the carrying amount of the investment is not considered to be recoverable due to reduced cash flows and changes to the entity's business model and strategic alignment with the Company.

hVIVO Services Limited continues to claim research and development tax credits for development of its human challenge models. The amount credited to the consolidated statement of comprehensive income (including amounts included within other income of £0.3 million), with respect to amounts received and receivable likely during the middle of 2019 for the surrender of research and development expenditure, was £2.4 million for the year ended 31 December 2018 (2017: £2.3 million).

## Balance sheet

The cost of investment in joint ventures and associates of £7.2 million (2017: £12.6 million) relates to Imutex Limited and reduced following the impairment in our investment in PrEP Biopharm Limited.

Short-term deposits and cash and cash equivalents were £13.4 million at 31 December 2018 (2017: £20.3 million). The principal cash flows in the year reflect outflows from operating activities £6.9 million (2017: £5.1 million), purchase of intangible assets and property, plant and equipment of £0.3 million (2017: £0.3 million) and finance income of £0.1 million (2017: £0.1 million).

An onerous lease and dilapidation provision of £1.2 million (2017: £2.3 million) represents management's best estimate of the costs to be incurred for the exit of premises leased. The majority of the provision will be used during 2019 and therefore has been reclassified to current liabilities as at 31 December 2018.

## Going concern

The Group's business activities, together with the factors likely to affect its future development, performance and position are set out in the strategic report on pages 1 to 21 and the Directors' report on pages 31 to 33.

In determining the basis for preparing the consolidated financial statements, the Directors are required to consider whether the Company can continue in operational existence for the foreseeable future, being a period of not less than twelve months from the date of the approval of the consolidated financial statements. As at 31 December 2018, the Group had cash and cash equivalents of £13.4 million (2017: £20.3 million) and net current assets of £7.7 million (2017: £17.6 million). At 31 March 2019, the Company's cash balance had reduced to £8.3 million with further outflows of £5.1 million through that date. The Company has historically been loss making given the level of research and development activity and has no borrowing facilities.

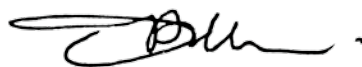
Management prepares detailed working capital forecasts which are reviewed by the Board on a regular basis. The forecasts include assumptions regarding the status of client engagements and sales pipeline, future revenues and costs together with various scenarios which reflect growth plans, opportunities, risks and mitigating actions. Management is in the process of refocussing the Company on its clinical development services business and away from its previous focus on research, which increases the uncertainty of contractual forecasts.

The Company has a relatively fixed cost base which means that in order to continue to operate as a going concern it has to win and deliver sufficient contracts to cover its cost base and operate within the cash resources it has. There is inherent uncertainty in all contract forecasts which is increased because of the current stage of the Company's development. A significant proportion of 2019 financial year forecast revenue is already contracted, however some of the revenue anticipated in the fourth quarter of 2019 and all of the forecast revenue for the first half of 2020 and beyond is dependent on winning and delivering new contracts.

Management has reviewed the contracts in the Company's order pipeline, discussed the likelihood of the contracts being placed with the counterparties, and in light of that, assessed the likelihood of the forecast revenue being achieved. Management's forecasts indicate that the Company will continue to incur cash outflows during 2019 and in the first half of 2020, but that thereafter, the Company will start to generate cash and that its current cash resources will be sufficient to enable it to continue to operate.

Although there is inherent uncertainty over the Company's forecasts and over the likelihood that the Company will win any individual contract, the Directors are satisfied that there are sufficient contracts in the pipeline such that they are satisfied that sufficient revenue will be generated to allow the Company to operate within its cash resources.

Having made relevant and appropriate enquiries, including consideration of the Company's and Group's current cash resources and the working capital forecasts, the Directors have a reasonable expectation that the Company and Group will have adequate cash resources to continue to meet the requirements of the business for at least the next twelve months. Accordingly, the Board continues to adopt the going concern basis in preparing consolidated financial statements.



**Dr Trevor Philips**

Executive Chairman

11 April 2019

# Principal risks and uncertainties

We operate within a complex regulatory environment which is subject to change and exposes the Company to a number of risks and uncertainties. We have developed and implemented a risk management process to help protect volunteers and safeguard patients, employees, Company assets and reputation and to help achieve business objectives.

hVIVO's Board of Directors is responsible for ensuring that the Group maintains an appropriate system of internal control. The system of control is designed to manage, rather than eliminate, the risk of failure to achieve business objectives. The risk profile of the Company's strategy and associated investments is continually monitored within hVIVO's corporate governance framework (see the corporate governance statement on pages 25 to 27). This section of the Annual Report and Financial Statements highlights the principal risks and uncertainties considered to have a material impact on the execution and delivery of hVIVO's financial and strategic objectives.



**Principal risk****Mitigation****Cancellation or delay of client contracts**

Our services business is the conduct of studies with experimental therapeutics therefore there is an inherent risk that a study may be cancelled, delayed or reduced in scope due to unexpected or undesired clinical results. Therefore we may not realise the full benefits of our backlog which could adversely impact our operating results and financial position.

- The terms of hVIVO's client contracts provide for any fees associated with the close-out of the study; this includes fees for activities performed to the date of termination, fees for close-out activities and recovery of any non-cancellable expenditures. Additionally, hVIVO negotiates the inclusion of postponement and cancellation fees in our contracts to compensate for a proportion of the lost revenue

**Competition**

If hVIVO does not keep pace with rapid technological change in the biopharmaceutical industry, our services may become less competitive or obsolete.

The emergence of competitors could impact our market potential and/or lead to pricing pressures and demand shortfall. Failure of our business development function to win new business under profitable contracts could adversely impact operating results and financial position.

- hVIVO employs experienced business development professionals to generate leads, win profitable new business and to gather market intelligence which helps hVIVO remain ahead of the competition
- hVIVO aims to ensure our high-quality services are provided at competitive rates by continually monitoring competitor developments and pricing positions
- hVIVO continues to focus on building and diversifying its service offerings in order to differentiate itself from its competitors
- hVIVO works to address its operating costs to ensure that it can provide its services at competitive rates

**Biopharmaceutical industry trends**

Our revenues depend on the level of research and development and regulatory compliance expenditure by biopharmaceutical companies. Accordingly, economic factors and industry trends that result in biopharmaceutical clients/potential clients either:

- reducing such expenditure, in particular the number of therapeutics entering clinical trials;
- reducing its outsourcing of clinical trials or outsourcing fails to grow at projected rates; or
- combining with another company and choosing to use the services of a competitor, and delaying/cancelling existing projects;

could adversely impact operating results and financial position.

- hVIVO seeks to maintain diversification in all aspects of its client base including:
  - type of client (large pharmaceutical, biotech, government and academia);
  - geography (US and Europe);
  - stage of therapeutic (Phase I through to post-approval); and
  - actively engages with its clients/potential clients to protect its existing relationships and to build new ones.

# Principal risks and uncertainties *continued*

Principal risk	Mitigation
<p><b>Regulatory, quality and ethics framework</b></p> <p>Failure to comply with legal, regulatory and ethical frameworks and/or regulations covering health and safety, Good Clinical Practice ("GCP"), MHRA, FDA and all other appropriate bodies resulting in:</p> <ul style="list-style-type: none"> <li>• core business being curtailed pending investigations for a period of time;</li> <li>• inability to deliver studies or closure;</li> <li>• data and sample integrity and/or subject safety being affected; and</li> <li>• potential legal action.</li> </ul>	<ul style="list-style-type: none"> <li>• hVIVO operates a single quality management system governed by senior quality and regulatory professionals to mitigate the risk of regulatory non-compliance. A Regulatory and Quality Governance Group provides governance over policies, standard operating procedures and corrective action/preventative action ("CAPA") processes. Regular internal audits are conducted and reported to management</li> <li>• hVIVO has instituted systems and training programmes to ensure adherence with policies and standard operating procedures</li> <li>• hVIVO's clinical governance framework ensures high quality, safe and accountable care of subjects by General Medical Council ("GMC") registered doctors</li> <li>• hVIVO complies with the UK Data Protection Act</li> </ul>
<p><b>Macroeconomic uncertainty following the UK's decision to exit from the EU ("Brexit")</b></p> <p>At this time, it is uncertain what impact the Brexit process will have on economic conditions and regulatory regimes in Europe, including in the UK. Adverse consequences such as deterioration in economic conditions, volatility in currency exchange rates or adverse changes in regulation could have a negative impact on our operating results and financial position.</p>	<ul style="list-style-type: none"> <li>• hVIVO seeks to maintain diversification in the geographic mix of its client base, with a significant proportion of clients/potential clients outside of Europe and the UK</li> <li>• The functional currency of the Company is Sterling for its sales and the majority of its purchases. hVIVO seeks to negotiate the majority of its contracts with international clients in Sterling; however, where this is not possible, hVIVO will seek to hedge against the foreign currency risk</li> </ul>
<p><b>Operations and business performance</b></p> <p>Failure to balance variable demand and utilisation against a fixed cost base would impact our operating results and financial position.</p> <p>Failure of third-party vendors to adequately provide products/services critical to our business could lead to failure to deliver against promise and would result in reputational risk.</p> <p>Poor operational controls could lead to failure to deliver against promise and would result in reputational risk.</p>	<ul style="list-style-type: none"> <li>• hVIVO continually assesses the permanent to variable staff ratio to ensure the business model operates efficiently</li> <li>• hVIVO has implemented a thorough contract review process to ensure third party vendors are appropriately vetted, inherent risks are identified and mitigated, and deliverables and obligations are clearly defined before contracts are finalised</li> <li>• hVIVO's Quality Management System and associated standard operating procedures support the safe, efficient and effective delivery of human challenge studies, covering start-up, recruitment and screening, quarantine and close-out activities</li> <li>• Improved scientific, financial and operational information sharing through the continued evolution of our reporting to better manage the business, reduces risk of errors and irregularities</li> <li>• Unexpected infectivity rates are an inherent risk to our business model, however they are a natural feature of a virus/human interaction. hVIVO exploits current scientific best practice and knowledge to provide the most appropriate circumstances and environment for infection to occur, although this cannot be guaranteed</li> </ul>
<p><b>Attraction and retention of key employees</b></p> <p>Challenges with attracting and retaining appropriate skills, knowledge and expertise could impact our ability to deliver against strategic and financial objectives.</p>	<ul style="list-style-type: none"> <li>• hVIVO benchmarks its remuneration and incentives packages and aims to ensure that they remain in line with industry standards</li> <li>• hVIVO is investing in leadership and management training to embed values and behaviours that will underpin a constructive, engaging and collaborative working environment</li> <li>• hVIVO undertakes talent identification and succession planning for key individuals and positions</li> </ul>

**Principal risk****Mitigation****Effectiveness and availability of information systems**

Our business depends on the continued effectiveness and availability of our information systems, including the information systems we use to provide services to our clients, and failures of these systems, including cyber-attacks or security breaches, may materially limit our operations or have an adverse effect on our reputation and cause us to lose clients.

Failure to effectively manage the implementation of upgrading information systems that support our operating processes and evolving the technology platform for our services in a timely and cost-effective manner may result in disruption to our business and negatively impact operations.

- IT incident, response and data recovery plans are in place to support overall business continuity plans
- hVIVO continues to invest in and embed measures across our IT infrastructure, systems and operational security to monitor and mitigate risks
- hVIVO continues to focus on cost-effective process enhancements to improve reporting and increase speed of information to the business thereby supporting better decision making and reducing risk of errors and irregularities

**Financial risk**

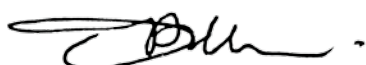
Failure to protect the Company's financial performance and stewardship of assets against financial risk.

- **Liquidity risk:** hVIVO maintains good relationships with its banks, financial institutions with high credit ratings, working capital requirements are anticipated via the forecasting and budgetary processes. Regular forecasting and reporting is in place to manage liquidity risk
- **Credit risk:** hVIVO is mainly exposed to credit risk from its trade and other receivables, short-term deposits and bank balances. An allowance for impairment is made where there is an identified loss event which, based on previous experience, is evidence of a reduction in recoverability of the cash flows
- **Foreign currency risk:** hVIVO is exposed to minimal foreign currency risk. The functional currency of the Company is Sterling for its sales and the majority of its purchases. hVIVO seeks to negotiate the majority of its contracts with international clients in Sterling; however, where this is not possible, hVIVO will seek to hedge against the foreign currency risk. Some third party supplier purchases are made in Euros and US Dollars, although these are not considered significant
- **Going concern:** we continue to monitor our cash position and forecast expenditure to ensure we operate within our available cash resources (see Going Concern analysis on page 17)

The Company's strategic report is set out on pages 1 to 21 of the Annual Report.

The strategic report outlines our performance against our strategic objectives, performance and financial position, as well as our outlook for the future.

The strategic report was approved by the Board on 11 April 2019 and signed on its behalf by:



**Dr Trevor Phillips**

Executive Chairman

11 April 2019



# Board of Directors



## Dr Trevor Phillips

Executive Chairman

### Appointment to the Board:

Dr Trevor Phillips was appointed to the hVIVO Board as a Non-Executive Director in June 2017 and subsequently Executive Chairman in November 2017.

### Experience and expertise

Trevor has over 30 years of experience within the pharmaceutical industry, including extensive international drug development and corporate development responsibilities. He was previously Chief Operations Officer and President of US Operations, as well as a member of the Board, at Vectura Group plc, a FTSE 250 company listed on the London Stock Exchange focussed on airways diseases. Subsequent to joining Vectura in 2010, Trevor played an integral leadership role in the company's successful development, including the acquisition of Activaero GmbH in 2014 and the merger with Skyepharma plc in 2016.

Prior to joining Vectura, Trevor held the roles of Chief Executive Officer and Chief Operating Officer at Critical Therapeutics, Inc. (now Chiesi USA, Inc.), a US listed specialty pharmaceutical company, where he was involved in setting up commercial partnerships, product in-licensing and out-licensing, managing drug development, commercial product manufacturing and M&A activity. He led the merger of Critical Therapeutics with Cornerstone BioPharma Holdings. He has also held senior management positions at Sepracor, Inc. (now Sunovion Pharmaceuticals, Inc.), Accenture plc and GlaxoWellcome plc (now GlaxoSmithKline plc).

Trevor trained as a microbiologist at University of Reading, obtaining a PhD in microbial biochemistry from the University of Wales in 1986. He was awarded an MBA from Henley Management College in 1997.

### Current external appointments

Trevor is currently Non-Executive Director at Morvus Technology Ltd and Non-Executive Director at NEPeSMO Ltd.



## Dr Trevor Nicholls

Senior Independent Non-Executive Director

### Appointment to the Board:

Dr Trevor Nicholls was appointed to the hVIVO Board as a Non-Executive Director in May 2014.

### Experience and expertise

Trevor is a professional Company Director with over 35 years of building international businesses in the life science industry, with a focus on genomics in major pharma, biotech and academic clients. Prior to joining CABI Trevor was Chief Commercial Officer for Affymetrix Inc with accountability for Sales, Marketing, Product Development and Manufacturing. Prior to this, he was founder CEO of Oxagen Ltd where he raised a total of £50 million over three venture-backed financing rounds and secured commercial partnerships in addition to academic collaborations.

A major part of his early career was with Amersham International (now part of GE Healthcare) covering diagnostics and radiopharmaceuticals as well as research products. He has also worked as a consultant with McKinsey and Company Inc. and in Marketing with Unilever.

Trevor holds a BA and D.Phil in biochemistry from the University of York and diploma qualifications in marketing (CIM) and company directorship.

### Current external appointments

Trevor is currently Chief Executive Officer at CABI and a Non-Executive Director at Avacta Group plc, Iota Sciences Ltd and Conidia Bioscience Ltd.

### Committees



### Key to committees:

Audit Committee

Remuneration Committee

Denotes chair of a committee





### Dr Mark Warne

Non-Executive Director

#### Appointment to the Board:

Dr Mark Warne was appointed to the hVIVO Board as a Non-Executive Director in April 2016 and is Chairman of the Remuneration Committee.

#### Experience and expertise

Mark is widely recognised in the UK and International life sciences sector, currently as a listed company Chief Executive and having spent almost ten years at IP Group Plc, a leading intellectual property commercialisation company, where he led the Healthcare team. He managed a portfolio of £330 million of net assets until 2017 and represented IP Group on the boards of both listed and private companies. Mark joined IP Group from pre-clinical drug discovery CRO, Exelgen, where he was Managing Director. He spent eight years at Exelgen (formerly Tripos Discovery Research) where he also held positions in licensing and strategic affairs, project management and research.

Mark has a PhD in Computational Chemistry, an MSc in Colloid Science and a BSc in Chemistry, all from the University of Bristol. Mark is a Chartered Chemist and member of the Royal Society of Chemistry.

#### Current external appointments

Mark Warne is Chief Executive Officer of DeepMatter Group plc and serves as a non-executive director on the board of Ixico plc.

#### Committees



### James F. Winschel

Non-Executive Director

#### Appointment to the Board:

James (Jim) Winschel was appointed to the hVIVO Board as a Non-Executive Director in October 2014 and is Chairman of the Audit Committee.

#### Experience and expertise

Following thirteen years as Senior Vice President and Chief Financial Officer of PAREXEL International Corporation (NASDAQ: PRXL), a leading biopharmaceutical services organization providing comprehensive drug development, consulting, medical communications, and technology services and solutions to the biopharmaceutical industry in over 100 countries, Jim was appointed Executive Vice President of PAREXEL in September 2013 until he retired in June 2014.

As CFO of PAREXEL, Jim was responsible for directing all financial activities, during a period when PAREXEL's revenue grew by \$1.5 billion, backlog increased by \$4.5 billion and PAREXEL's market capitalisation increased from \$225 million to \$2.8 billion. The Company was recently sold to private equity for \$4.5 billion.

Earlier in his career, Jim spent five years at BTM Capital Corporation, a Bank of Tokyo-Mitsubishi Ltd. subsidiary, initially as Executive Vice President and Chief Financial Officer for three years from 1995 before being promoted to President, U.B. Vehicle Leasing, Inc. until 2000.

Prior to these roles, he was Vice President – Finance, Physician Services Division at Caremark International, Inc. for two years from 1993 and spent the previous four years at Whirlpool Financial Corporation ("WFC"), both as the Vice President and Managing Director, Commercial Financing Division and prior to that as the Vice President and Chief Financial Officer. Jim worked for five years in various roles at General Electric Capital Corporation, in the Transportation and Industrial Financing Division and prior to that at General Electric Company for eleven years.

Jim holds an MBA in Accounting and a BSc in Finance from Syracuse University in the USA.

#### Current external appointments

Jim is CFO of Hamlin Scientific Corporation in Boston, MA and CFO of Vivtex Corporation in Cambridge, MA.

#### Committees



# Executive Leadership Team

In addition to the Board, the Company has an Executive Leadership Team which consists of the Executive Chairman and four senior members of the management.



**Tim Sharpington**

Chief Operating Officer

Tim brings to hVIVO more than 25 years' experience in the life sciences sector with various pharmaceutical, biotechnology and pharmaceutical service companies in Europe and the US. He has broad experience in drug development, product licensing, mergers, acquisitions and fundraisings. Tim's previous positions include chief executive officer at Phytopharm plc and Serentis Limited and executive vice president at Vectura plc, a UK company also focussed on airways disease. Tim is a non-executive director and senior independent director of Ixico plc.



**Shelley Fraser**

Finance Director and Company Secretary

Shelley joined hVIVO as Vice President, Finance and was appointed Finance Director and Company Secretary in January 2019. Shelley has over 18 years' experience in the pharmaceutical, biotech and life sciences industry, operating in service and product offering environments. A chartered accountant, she has worked in Asia Pacific and Europe, reporting to US blue chip companies, Merck and Thermo Fisher Scientific. Shelley has spent more than 15 years as Finance Director, with broader responsibilities covering facilities, supply chain, IT and HR.



**Reid Tripp**

Executive Vice President,  
Business Development and Marketing

Before joining hVIVO, Reid held senior management business development and marketing positions with various large, mid-sized and small global clinical research organisations where he successfully built and managed sales, marketing, proposals and contracts teams, delivered hundreds of millions in contractual relationships and overall, enhanced customer satisfaction. Reid has also served in a senior management role at a start-up biotechnology company and has held various management positions for a large pharmaceutical company.



**Fleur Wood**

Executive Vice President,  
Investor Relations and Communications

Fleur brings over 20 years' experience in investor relations, communications and capital markets gained primarily within the UK investment banking industry and the pharmaceuticals sector. During her career, she has brought strategic IR skills to both M&A situations and to companies undergoing growth and change.

Fleur's previous role was at Vectura Group plc, a FTSE 250 company listed on the London Stock Exchange focussed on airways diseases, where she held positions as director of communications and director of investor relations. She played an integral role in the acquisition of Activaero GmbH in 2014 and the merger with Skyepharma plc in 2016.

# Corporate governance statement

The Board of hVIVO plc (“hVIVO” or the “Company”, or together with its subsidiaries, the “Group”) is responsible for the Group’s corporate governance policies and recognises the importance of this in creating a sustainable, growing and profitable business.

The Company has adopted the Quoted Companies Alliance Corporate Governance Code (the “QCA Code”). This statement sets out how the Company complies with the Quoted Companies Alliance’s Ten Principles of Corporate Governance. The full narrative is shown on the hVIVO website [www.hvivo.com](http://www.hvivo.com).

## 1. Strategy and business model

Our vision is to become the partner of choice for companies developing products in airways disease that are seeking to gain early proof-of-concept around the effectiveness of their products and identify the ideal patient profile for later-stage clinical development. We are committed to a strategy of driving revenue growth and cash generation and in turn leading to sustained profitability. Such financial discipline also necessitates the need to exercise ongoing tight cost control and implementation of efficiency programmes to ensure we drive towards profitability in 2019, as referenced on pages 12 and 13.

## 2. Understanding and meeting shareholder needs and expectations

hVIVO is committed to listening to, and communicating openly with, our shareholders to ensure our strategy, business model and performance are clearly understood and supported. Understanding what investors and analysts think about us, and in turn, helping these audiences understand our business, is a key part of driving our business forward and we actively seek dialogue with the market.

We do so via investor roadshows and ad hoc meetings with both existing and potential new shareholders, attending investor conferences, hosting scientific days and our regular financial results reporting.

## 3. Wider stakeholder and social responsibilities and their implications for long-term success

hVIVO’s stakeholders include shareholders, employees, clients, suppliers, regulatory authorities, government organisations and the scientific community at large.

We regularly present at scientific conferences and have a comprehensive publications strategy, in order to be at the forefront of, and a contributor to, scientific leadership in respiratory and infectious diseases.

hVIVO is subject to, and operates within, the highly regulated human clinical trial environment and is fully compliant with Good Clinical Practice (“GCP”) and where relevant, Good Manufacturing Practice (“GMP”) and for laboratories. Notwithstanding the foregoing, human viral challenge studies continue to be a very specialised and developing area.

We therefore consult with regulatory authorities (e.g. the MHRA, Research Ethics Committees and other ethics bodies, US Food and Drug Administration, European Medicines Agency, Human Tissue Authority, etc), government organisations and funding bodies (such as US National Institutes of Health, US Biomedical Advanced Research and Development Authority), universities and scientific thought leaders, to define and ensure best practice in the conduct of human viral challenge studies; and the manufacture, testing, use and regulation of challenge agents, particularly viruses.

We are always engaged in dialogue with pharmaceutical and biotech companies, whether as part of our business development process or when contracted as clients and undertaking their clinical studies.

We communicate thoroughly with all stakeholders and use the experience we gain from those interactions and from conducting the clinical services to further develop our service offerings. As a result, we remain at the forefront in the development and execution of human challenge studies in airways diseases.

## 4. Embedding effective risk management

Risk management at hVIVO is an integral part of decision making and is embedded in normal business operations. It exists to help protect and safeguard volunteers, employees, clients, Company assets and reputation and to help achieve business objectives as referred to principal risks and uncertainties on pages 18 to 21.

# Corporate governance statement continued

## 5. Maintaining a balanced and well-functioning board

Dr Trevor Phillips was appointed as Executive Chairman on 13 November 2017 and took on Kym Denny's responsibilities as Chief Executive Officer when she stepped down on 18 April 2018. Other changes to the Board during the year were Jaime Ellertson, Non-Executive Director, who stepped down on 8 October 2018 and Graham Yeatman, Chief Financial & Business Officer, who resigned on 31 December 2018. Accordingly, from 1 January 2019, the Board of hVIVO plc comprises one Executive Director and three Non-Executive Directors. The Board continues to review the combined role of Dr Trevor Phillips to ensure adequate oversight and evaluation of the performance of senior officers and the Company is maintained.

To support this consideration, the Board has also approved two observers to attend Board meetings, Shelley Fraser, Finance Director and Company Secretary, and Tim Sharpington, Chief Operating Officer.

In the short term, and during the current period of hVIVO achieving its strategy to refocus as a services business and drive revenue growth, profitability and cash generation, it is felt appropriate that Dr Trevor Phillips performs the role of both Executive Chairman as well as the responsibilities of the Chief Executive Officer. The Board accepts that it is normally more appropriate to separate the roles but believes that this is mitigated in the short term by Dr Trevor Nicholls acting as Senior Independent Director, to act as a sounding board and intermediary for the Chairman and other Board members as necessary.

The Board considers that all three Non-Executive Directors are independent, noting the following points identified as potentially impacting their independence. The Board is satisfied that it has a suitable balance between independence on the one hand, and knowledge of the Company on the other, to enable it to discharge its duties and responsibilities effectively.

All Directors are encouraged to use their independent judgement and to challenge all matters, whether strategic or operational. The Executive Chairman holds regular update meetings with each Director to ensure they are performing as they are required.

## 6. Having appropriate experience, skills and capabilities on the board

The Board is satisfied that, between the Directors, it has an appropriate balance of life sciences, financial and public markets skills and experience, as well as an appropriate balance of personal qualities and capabilities. The biographies of each of the Directors is shown on pages 22 and 23 and the hVIVO website (<http://hvivo.com/aboutus/board-of-directors/>).

The role of the Non-Executive Directors is to bring valuable judgement and insight to Board deliberations and decisions. The Non-Executive Directors are all experienced and influential individuals whose blend of skills and business experience contributes to the proper functioning of the Board and its Committees, ensuring that matters are fully debated and that no individual or group dominates the Board's decision-making processes.

Under the Articles of Association, all Directors must offer themselves for re-election at least once every three years. One-third of the Directors retire by rotation at every Annual General Meeting and are eligible for re-appointment.

All Directors have access to the advice and services of the Company Secretary and in the course of their duties, if necessary, are able to take independent professional advice at the Company's expense. Committees have access to such resources as are required to fulfil their duties.

## 7. Evaluating board performance

During 2019 we intend to review the performance of the Board as a unit, as well as that of its committees and the individual Directors, to ensure that the members of the Board collectively function in an efficient and productive manner.

All Directors will undergo a performance evaluation before being proposed for re-election to ensure that their contribution continues to be relevant and effective, that they are demonstrating continued commitment to the role and that, where appropriate, they maintain their independence.

From April 2019, the Senior Independent Director will appraise the Executive Chairman on an annual basis and in making recommendation to the Remuneration Committee for award of annual bonus.

## 8. Ethical values and behaviours

The Group conducts its business in a socially responsible manner, with our values of integrity, innovation, growth and one team at the core of our culture. These values are held accountable by the Board, communicated to all staff and demonstrated by our actions. Our staff handbook and standard operating procedures outline the fundamentals of our values to all staff (including business integrity, anti-bribery, gifts, intellectual property, etc). We ensure the embedding of our values and policies through regular emphasis in training, development and performance objectives.

The Group operates internationally, and we are mindful that respect of individual cultures is critical to corporate success. We always strive to conduct our business in an ethical, professional and responsible manner, treating our employees, customers, suppliers and partners with equal courtesy and respect.

The Group is committed to providing equal opportunities in employment and the creation of a work environment where everyone is treated with dignity and respect. The Group has developed and implemented policies and processes to ensure that all job applicants and employees receive equal treatment regardless of gender, race, age, disability, sexual orientation, religion or belief, nationality or ethnic origin.

The Group places considerable value on the engagement and involvement of our employees and keeps them informed on matters affecting them as employees and on the various factors affecting the performance of the Group.

The Remuneration Committee oversees hVIVO's reward policy and practices to support the creation of competitive practices which are designed to support a pay for performance culture throughout the organisation whilst also ensuring that we balance commercial drivers with our regulatory responsibilities.

## 9. Maintaining governance structures and processes

The Board of Directors has overall responsibility for the Group. Its aim is to represent the interests of the Group's shareholders and to provide leadership and control to ensure the growth and development of a successful business.

The Board is responsible for the review and approval of key policies and decisions in respect of business strategy and operations, Board appointments, budgets and forecasts, items of substantial investment and acquisitions. The Board receives regular and timely reports detailing the progress of the Group, the Group's financial position and projections, as well as business development activities and operational issues, together with any other documentation and briefing deemed necessary for the Board to discharge its duties. Management prepares detailed working capital forecasts which include assumptions regarding the status of client engagements, sales pipeline and contract signatures, future revenues and costs together with various scenarios which reflect growth plans, opportunities, risks and mitigating actions. Relevant documentation, including minutes of previous meetings (for Board review and approval), is circulated to the Directors in advance of meetings.

The Executive Chairman is primarily responsible for the effective operation and chairing of the Board and for ensuring that it receives appropriate information to make informed judgements.

The Board has a formal schedule of matters reserved to it for decision, but otherwise delegates specific responsibilities to the Audit Committee and Remuneration Committee. The terms of reference of the Committees are provided on the hVIVO website (<http://hvivo.com/investors/aimrule26/>).

## 10. Communicating how the company is governed and maintaining a dialogue with shareholders and other relevant stakeholders

The Board attaches great importance to communication with both institutional and private shareholders in reporting and demonstrating good corporate governance practices to create a sustainable, growing, profitable and successful business.

As noted in our application of Principle 2, and in seeking to understand and meet our shareholder needs and expectations, regular communication is maintained with all shareholders through the Company's Annual General Meeting, Company announcements, the Annual Report and Financial Statements, Preliminary Statements and Half-year Report.

The Company operates a website at [www.hvivo.com](http://www.hvivo.com). The website contains details of the Group and its activities, regulatory announcements and Company announcements, Annual Reports and Half-year Reports, notices of all general meetings, and the Terms of Reference of the Audit and Remuneration Committees.



# Directors' remuneration report

**hVIVO's remuneration practice is to encourage and reward individual superior performance in line with both corporate and individual performance goals linked to the delivery of value to our shareholders.**

## Introduction

hVIVO plc has elected voluntarily to prepare a Directors' remuneration report as set out below.

As a company admitted to trading on AIM, the Company is not required to provide a formal remuneration report. This report is provided to give greater transparency of the Group's remuneration policy.

## Remuneration practice overview

hVIVO's remuneration practice is to encourage and reward individual superior performance in line with both corporate and individual performance goals linked to the delivery of value to our shareholders.

The Remuneration Committee oversees hVIVO's reward policy and practices to support the creation of competitive practices which are designed to support a pay-for-performance culture throughout the organisation whilst also ensuring that we balance commercial drivers with our regulatory responsibilities.

Our approach is designed to offer rewards that:

- drive a culture of pay for performance;
- enable hVIVO to attract and retain the talent it needs to ensure success;
- incentivise the achievement of the Group's strategy and build sustainable long-term performance;

- have the flexibility to accommodate the changing needs of the business as it grows and responds to customer needs and new business opportunities;
- incentivise achievement linked to growth goals aligned with our current stage of growth and development; and
- attract, retain and reward the senior executive team and from time to time selected other key individuals with critical skills, engendering a collective opportunity to drive performance and share in the success and growth of the business if they successfully deliver increased shareholder value.

The Company's remuneration practice is reviewed on an annual basis by the Company's Remuneration Committee to ensure it remains aligned with the Company's objectives and shareholders' interests.

## Executive Directors

Trevor Phillips has a service agreement with hVIVO plc dated 27 October 2017 with effect from 13 November 2017. His appointment is terminable on six months' notice by either party.

Kym Denny had a service agreement with hVIVO plc dated 26 April 2012, with continuous employment from 28 September 2009. Her appointment was terminable on six months' notice by either party. Kym Denny stepped down as Chief Executive Officer on 18 April 2018.

Graham Yeatman had a service agreement with hVIVO plc dated 15 April 2015, with continuous employment from 3 May 2011. His appointment was terminable on six months' notice by either party. Graham Yeatman stepped down as Chief Financial and Business Officer on 31 December 2018.

## Non-Executive Directors

The Non-Executive Directors have entered into letters of appointment with the Company, with the Board determining any fees paid. The appointments are terminable on three months' notice by either party. The Non-Executive Directors do not participate in the Group's pension, bonus or option schemes. Options previously awarded to Trevor Nicholls by Activiomics Limited were, following acquisition, exchanged for hVIVO options on a like-for-like basis. Professional services were provided to the US-based Non-Executive Directors for the preparation and submission of their annual UK tax return. Jaime Ellertson resigned as Non-Executive Director on 5 October 2018.

## Remuneration

The Executive Directors, Trevor Phillips, Kym Denny and Graham Yeatman, were entitled to receive a base salary, travel allowance, employer pension contributions, share options and a discretionary performance-related bonus.

## Salary

Base salaries are reviewed annually and effective from the beginning of April.

The Remuneration Committee seeks to assess the market competitiveness of pay primarily in terms of total remuneration, with less emphasis on base salary.

## Benefits

During 2016, the Company implemented a flexible benefit platform, providing a much more engaging approach to the overall management and visibility of total reward for employees as well as introducing benefit enhancements for all employees of life insurance and healthcare solutions.

The Executive Directors are entitled to receive a benefit of life insurance (three times base salary) and private medical insurance (self and family).

## Bonuses

The timing and amount of bonuses are decided by the Remuneration Committee with reference to the individual's performance and contribution to the Group. The maximum bonus that can be earned by an Executive Director is 100% of base salary. The annual bonus may be payable partly as cash and partly as nominal cost options, vesting on the second anniversary of the date of grant, with split determined at the discretion of the Remuneration Committee.

## Pensions

The Group operates a Group personal pension scheme which is a defined contribution scheme. The scheme is open to the Executive Directors and all employees. Under the scheme rules, the Group pays an employer pension contribution to the Executive Directors of 9% of base salary. The Executive Directors may elect to receive a like-for-like cash allowance in lieu of employer pension contribution if advised due to lifetime allowance constraints.

## Directors' remuneration

The Directors received the following remuneration during the year:

	Salary and fees <sup>1</sup> £'000	Taxable benefits £'000	Bonus £'000	Loss of office £'000	2018 total excluding pensions £'000	2018 pensions £'000	2017 total excluding pensions £'000	2017 pensions £'000
Trevor Phillips	280	1	—	—	281	6	31	—
Kym Denny <sup>2</sup>	135	1	—	128	264	11	301	23
Graham Yeatman <sup>3</sup>	228	1	—	137	366	—	259	—
<b>Executive Directors</b>	<b>643</b>	<b>3</b>	<b>—</b>	<b>265</b>	<b>911</b>	<b>17</b>	<b>591</b>	<b>23</b>
Jaime Ellertson <sup>4</sup>	13	—	—	—	13	—	135	—
Trevor Nicholls	20	—	—	—	20	—	20	—
Trevor Phillips	—	—	—	—	—	—	17	—
Mark Warne	20	—	—	—	20	—	20	—
James Winschel <sup>5</sup>	50	—	—	—	50	—	50	—
<b>Non-Executive Directors</b>	<b>103</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>103</b>	<b>—</b>	<b>242</b>	<b>—</b>
<b>Total</b>	<b>746</b>	<b>3</b>	<b>—</b>	<b>265</b>	<b>1,014</b>	<b>17</b>	<b>833</b>	<b>23</b>

\* Amounts above have been audited.

1. Salary and fees including travel allowances and cash allowances in lieu of employer pension contribution.

2. Kym Denny stepped down as CEO on 18 April 2018.

3. Graham Yeatman stepped down as Chief Financial & Business Officer on 31 December 2018.

4. Jaime Ellertson's disclosed remuneration includes an amount which is contractually committed by him quarterly to purchase shares of hVIVO plc. Jaime Ellertson stepped down as Non-Executive Director on 5 October 2018.

5. James Winschel's disclosed remuneration includes an amount which is contractually committed by him quarterly to purchase shares of hVIVO plc.

# Directors' remuneration report *continued*

## Share options

The Company issues share options to the Executive Directors and employees to reward performance, to encourage loyalty and to enable valued employees to share in the success of the Company.

Aggregate emoluments disclosed above do not include any amounts for the value of options to acquire ordinary shares in the Company granted to or held by the Directors.

	Options as at 31 December 2017	Number of options granted during the year	Number of options exercised during the year	Number of options forfeited during the year	Options as at 31 December 2018	Date of grant	Expiry of option	Exercise price	Percentage vested
Trevor Phillips	850,000	—	—	—	<b>850,000</b>	20 Dec 17	19 Dec 27	5.00p	—
Kym Denny <sup>1</sup>	145,540	—	145,540	—	—	13 Jan 10	12 Jan 20	6.25p	100
	1,366,320	—	1,366,320	—	—	23 Dec 11	22 Dec 21	8.15p	100
	111,193	—	—	111,193	—	21 Apr 15	20 Apr 25	337.25p	100
	32,813	—	—	8,203	<b>24,610</b>	17 May 17	16 May 27	5.00p	—
Graham Yeatman	644,600	—	—	—	<b>644,600</b>	23 Dec 11	22 Dec 21	8.15p	100
	88,955	—	—	—	<b>88,955</b>	21 Apr 15	20 Apr 25	337.25p	100
	26,250	—	—	—	<b>26,250</b>	17 May 17	16 May 27	5.00p	—
	—	100,000	—	—	<b>100,000</b>	10 Aug 18	9 Aug 21	5.00p	—
Trevor Nicholls	26,540	—	—	—	<b>26,540</b>	3 Mar 14	18 Dec 22	101.63p	100

1. Kym Denny was not a director at the point of exercising of options.



# Directors' report

## Financial statements

The Directors present their Annual Report and audited financial statements for the Company (registered company number 08008725) and Group for the year ended 31 December 2018.

## Principal activities

hVIVO is an industry-leading clinical development services business pioneering human disease models based upon viral challenge. Using human challenge studies to establish early proof-of-concept, hVIVO's clinical trial platform can accelerate drug and vaccine development in respiratory and infectious diseases, specifically leveraging hVIVO's established human disease challenge models in influenza ("flu"), respiratory syncytial virus ("RSV") and human rhinovirus ("HRV") and more recently the expansion and development of these models in other respiratory indications for asthma, chronic obstructive pulmonary disease ("COPD"), cough and related new therapies and in special populations. Based in the UK, hVIVO has conducted more than 50 clinical studies, inoculated over 2,700 volunteers.

The operational activities of the Group are carried out through hVIVO Services Limited, a 100% owned subsidiary of hVIVO plc. The principal activity of the Company is that of a holding company.

## Business review and key performance indicators

The Group's results are set out in the consolidated statement of comprehensive income on page 42 and are explained in the financial review on pages 16 and 17. A detailed review of the business, its results and future direction is included in the Executive Chairman's statement on pages 8 to 11.

## Capital structure

The Company is primarily financed through equity provided by its shareholders.

The Company has one class of ordinary shares which carry no right to fixed income. Each share carries the right to one vote at general meetings of the Company.

There are no restrictions on the size of a holding nor on the transfer of shares, which are both governed by the Articles of Association and prevailing legislation. The Directors are not aware of any agreements between holders of the Company's shares that may result in restrictions on the transfer of securities or on voting rights.

Details of employee share schemes are set out in note 25.

No person has any special rights of control over the Company's share capital and all issued shares are fully paid.

With regard to the appointment and replacement of Directors, the Company is governed by its Articles of Association, the Companies Act and related legislation. The articles themselves may be amended by special resolution of the shareholders.

Details of financial risk management are set out in note 23.

## Research and development

The Group considers that the majority of its activities constitute research and development, whether as separate independent research and development (separately identified as research and development expense in the consolidated statement of comprehensive income), or as a natural consequence of operating and pioneering human disease models during client sponsored human disease model studies (included within cost of sales). In the opinion of the Directors, continuity of the investment in this area is essential for the development of the human disease model, maintenance of the Group's market position and for achieving long-term significant value.

## Dividends

The Directors do not recommend the payment of a dividend (2017: £nil).

## Directors

The Directors of the Company are as follows:

- Trevor Phillips;
- Kym Denny – stepped down as Chief Executive Officer on 18 April 2018;
- Graham Yeatman – resigned as Chief Financial and Business Officer on 31 December 2018;
- Jaime Ellertson – stepped down as Non-Executive Director on 5 October 2018;
- Trevor Nicholls;
- Mark Warne;
- James Winschel; and
- Dr Trevor Phillips – appointed as Executive Chairman on 13 November 2017 and took on Kym Denny's responsibilities as Chief Executive Officer when she stepped down on 18 April 2018 as reported on page 11.

# Directors' report continued

## Directors continued

At 31 December 2018, the Directors had the following beneficial interests in the Company's shares:

	31 December 2018 Number	31 December 2017 Number
<b>Executive Directors</b>		
Trevor Phillips	32,535	9,035
<b>Non-Executive Directors</b>		
James Winschel	79,558	50,123
Mark Warne	5,677	5,677

Biographical details of the Directors who are not retiring are given on pages 22 and 23.

## Directors' interests

The interests of Directors in the shares of the Company are given above and in the Directors' remuneration report on pages 28 to 30.

Directors' interests in contracts of significance, other than service contracts are disclosed in note 28 to the financial statements. Information regarding Directors' service contracts is given on page 28 within the Directors' remuneration report.

## Directors' and officers' liability insurance and indemnity

The Company has purchased insurance to cover the Directors and officers of the Company and that insurance remains in force at the date of this report. The insurance operates to protect the Directors and officers by providing qualifying third-party indemnity provisions.

## Share capital

During 2018, 56,167 ordinary shares were allotted pursuant to the quarterly purchase of shares by Jaime Ellertson and James Winschel under the terms of their letters of appointment.

As at 31 December 2018, the issued share capital of the Company was:

	Number of ordinary 5p shares	Nominal value £
Issued and fully paid up	80,593,592	4,029,680

The average market price of the Company's ordinary shares at close of business on 31 December 2018 was 27.35 pence per share.

The maximum share price during the year was 101.0 pence per share (5 July 2018) and the minimum price was 17.0 pence per share (25 May 2018).

During 2019 to date, 29,887 ordinary shares were allotted pursuant to the quarterly purchase of shares by James Winschel under the terms of his letter of appointment

## Substantial share interests

At 11 April 2019, the Company had been advised or is aware of the following interests of 3% or more in the Company's issued share capital:

	Number of shares	Percentage of issued share capital
Woodford Investment Management	24,173,760	29.15
Invesco	21,249,382	25.62
IP Group	13,063,883	15.75
Hargreaves Lansdown, stockbrokers (EO)	3,205,568	3.86
Alliance Trust Savings	2,613,722	3.15

## Employees

The Group is committed to providing equal opportunities in employment and creation of a work environment where everyone is treated with dignity and respect. All job applicants and employees receive equal treatment regardless of gender, race, age, disability, sexual orientation, religion or belief, nationality or ethnic origin.

The Group places considerable value on the involvement of our employees and keeps them informed on matters affecting them as employees and on the various factors affecting the performance of the Group. This is achieved through newsletters, formal and informal meetings, either directly with employees, or through an Employee Representatives Group ("ERG") – consisting of representatives from various business constituencies appointed by and acting on behalf of our employees. ERG is actively involved in the work of Employee Forum, a collaborative platform for the engagement of employees and sharing of management information. The Annual and Half-year Reports and Financial Statements are also key milestones in communicating with our employees.

hVIVO recognises that commercial success depends on the full commitment of all our employees and commits to respecting their human and employment rights, to provide them with a good, challenging and fulfilling working environment, free from unnecessary risk, and to maintain fair and competitive terms and conditions of employment at all times.

Applications for employment by people with disability are always fully considered, bearing in mind the respective aptitudes and abilities of the applicant concerned and our ability to make reasonable adjustments to the role and the work environment. In the event of existing employees becoming disabled, all reasonable effort is made to ensure that their employment within the Group continues. Training, career development and promotion of a disabled person is, as far as possible, identical to that of an able-bodied person.

## Subsequent events

There are no events after the balance sheet date requiring disclosure.

## Auditor

Each of the persons who is a Director at the date of approval of this Annual Report and Financial Statements confirms that:

- so far as the Director is aware, there is no relevant audit information of which the Company's auditor is unaware; and
- the Director has taken all the steps that he or she ought to have taken as a Director to make themselves aware of any relevant audit information and to establish that the Company's auditor is aware of that information.

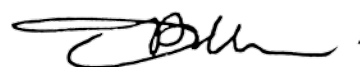
This confirmation is given and should be interpreted in accordance with the provisions of section 418 of the Companies Act 2006.

Ernst & Young LLP was appointed on 29 December 2016 as the Company's auditor. Ernst & Young LLP has expressed its willingness to continue in office as the Company's auditor and a resolution to re-appoint it will be proposed at the forthcoming Annual General Meeting.

## Annual General Meeting

The Notice convening the Annual General Meeting, which will take place at 10:00am on 30 May 2019 at the Company's registered office, has been sent out to shareholders with the Annual Report and Financial Statements. Details of the business to be transacted at the AGM can be found in the Notice.

By order of the Board



**Dr Trevor Phillips**

Executive Chairman

11 April 2019

## Directors' responsibilities statement

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

Company law requires the Directors to prepare Group and Company Financial Statements for each financial year.

The Directors are required by the AIM Rules of the London Stock Exchange to prepare Group Financial Statements in accordance with International Financial Reporting Standards ("IFRSs") as adopted by the European Union ("EU") and have elected under company law to prepare the Company Financial Statements in accordance with IFRSs as adopted by the EU.

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 Group for that period. In preparing each of the Group and Company Financial Statements, the Directors are required to:

- select suitable accounting policies and then apply them consistently;
- make judgements and estimates that are reasonable and prudent;
- state whether they have been prepared in accordance with applicable IFRSs as adopted by the EU; and
- prepare the Financial Statements on the going concern basis unless it is inappropriate to presume that the Group and the Company will continue in business.

The Directors are responsible for keeping adequate accounting records that are sufficient to show and explain the Group's and the Company's transactions and disclose with reasonable accuracy at any time the financial position of the Group and the Company 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 Group and the Company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

The Directors are responsible for the maintenance and integrity of the corporate and financial information included on the Company's website. Legislation in the United Kingdom governing the preparation and dissemination of financial information differs from legislation in other jurisdictions.

# Independent auditor's report

to the members of hVIVO plc

## Opinion

### In our opinion:

- hVIVO plc's Group financial statements and parent company financial statements (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 2018 and of the Group's loss for the year then ended;
- the Group financial statements have been properly prepared in accordance with IFRSs as adopted by the European Union;
- the parent company financial statements have been properly prepared in accordance with IFRSs as adopted by the European Union and as applied in accordance with the provisions of the Companies Act; and
- the financial statements have been prepared in accordance with the requirements of the Companies Act 2006.

We have audited the financial statements of hVIVO plc which comprise:

Group	Parent company
Consolidated statement of financial position as at 31 December 2018	Statement of financial position as at 31 December 2018
Consolidated statement of comprehensive income for the year then ended	Statement of changes in equity for the year then ended
Consolidated statement of changes in equity for the year then ended	Statement of cash flows for the year then ended
Consolidated statement of cash flows for the year then ended	Related notes 1 to 11 to the financial statements including a summary of significant accounting policies
Related notes 1 to 30 to the financial statements, including a summary of significant accounting policies	

The financial reporting framework that has been applied in their preparation is applicable law and International Financial Reporting Standards ("IFRSs") as adopted by the European Union and, as regards to the parent company financial statements, as applied in accordance with the provisions 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 below. We are independent of the Group and parent 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 relating to going concern

We have nothing to report in respect of the following matters in relation to which the ISAs (UK) require us to report to you where:

- the Directors' use of the going concern basis of accounting in the preparation of the financial statements is not appropriate; or
- the Directors have not disclosed in the financial statements any identified material uncertainties that may cast significant doubt about the Group's or the parent company's ability to continue to adopt the going concern basis of accounting for a period of at least twelve months from the date when the financial statements are authorised for issue.

# Independent auditor's report continued

to the members of hVIVO plc

## Overview of our audit approach

Key audit matters	<ul style="list-style-type: none"> <li>Revenue recognition for service contracts.</li> <li>Valuation of investments in joint ventures and associates.</li> <li>Going concern.</li> <li>Carrying value of parent company investments in subsidiary.</li> </ul>
Audit scope	<ul style="list-style-type: none"> <li>We performed an audit of the complete financial information of one component and audit procedures on specific balances for a further two components.</li> <li>The components where we performed full or specific audit procedures accounted for 100% of operating expenses, 100% of revenue and 100% of total assets.</li> </ul>
Materiality	<ul style="list-style-type: none"> <li>Overall Group materiality of £158,000, which represents 1% of operating expenses.</li> </ul>

## Key audit matters

Key audit matters are those matters that, in our professional judgement, 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) that we identified. These matters included 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 our opinion thereon, and we do not provide a separate opinion on these matters.

Risk	Our response to the risk	Key observations communicated to the Audit Committee
<p><b>Revenue recognition under the percentage of completion method (2018: £11.0 million, 2017: £10.8 million).</b></p> <p>Accounting policies (page 46); and note 5 of the consolidated financial statements (page 60).</p> <p>The Group recognises revenue from clinical trial services provided to customers using service contract milestones and percentage of completion when recognising revenue over time. The percentage of completion is determined using output measures, being the level of work completed to date in respect of each individual element of the clinical services contract. 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.</p> <p>We identified a risk of inaccurate or incomplete recognition of revenue due to the incorrect allocation to service contract milestones, and the application of incorrect 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.</p>	<p>We have performed the following audit procedures:</p> <ul style="list-style-type: none"> <li>assessed the appropriateness of the Company's revenue recognition accounting policies;</li> <li>performed a walk-through of the process followed and related controls with regard to the recognition of revenue;</li> <li>reviewed all contracts with customers and tested that the Company has correctly accounted for the revenue arising from these contracts in accordance with the accounting policies;</li> <li>performed detailed testing on individually significant contracts, including substantiating a sample of transactions with underlying documents such as contracts, progress metrics data, internal cost forecasts and project completion reports, as well as discussions with project managers;</li> <li>performed a recalculation of management's revenue model to determine project revenue recognised is appropriate and in line with the policy; and</li> <li>evaluated whether revenue has been appropriately presented and disclosed in the financial statements.</li> </ul>	<p>We are satisfied that management have appropriately accounted for revenue in line with the accounting policy.</p> <p>We are also satisfied that management have appropriately disclosed their transition to IFRS 15 adequately in the consolidated financial statements.</p>

Risk	Our response to the risk	Key observations communicated to the Audit Committee
<p><b>Valuation of investments in joint ventures and associates</b></p> <p>Note 3 critical accounting estimates and judgements (page 54); and note 17 of the consolidated financial statements (page 66) and note 3 of the parent company financial statements.</p> <p>There is a risk of incorrect valuation of equity accounted balances held by hVIVO plc. Given the nature of early stage research and development activities, there is a higher risk of failure of research programmes, which increases the risk of inaccurate valuation of investments.</p> <p>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.</p>	<p>We have performed the following audit procedures:</p> <ul style="list-style-type: none"> <li>• obtained and reviewed management's assessment of impairment of the joint venture and associate;</li> <li>• validated key judgements by agreeing to supporting documentation;</li> <li>• where no indicators of impairment were found, challenged the judgements made in management's assessment regarding any potential indicators of impairment;</li> <li>• where indicators of impairment have been found, challenged management's assessment of the recoverable amount of the associate or joint venture;</li> <li>• confirmed that there is no current commercial opportunity for the associate; and</li> <li>• considered the appropriateness of the Company's disclosures in relation to any impairment in the financial statements.</li> </ul>	<p>We are satisfied that management have appropriately accounted for the impairment loss on the associate.</p> <p>We are also satisfied that the disclosure in both the consolidated financial statements and the parent Company financial statements is appropriate and in line with the Company's accounting policy.</p>
<p><b>Going concern</b></p> <p>Note 2 of the consolidated financial statements (page 46).</p> <p>Management judgement is required in assessing whether the Company is a going concern as it has historically incurred losses, does not have borrowing facilities and is in the process of refocussing its business activity on its clinical development services business. The refocussing of the business makes it more difficult to forecast future contractual revenue .</p> <p>The key assumptions that impact the conclusions are the levels of future revenue, and the ability to control the operating costs.</p> <p>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 Company will not be able to operate within its cash resources and continue to operate as a going concern.</p>	<p>We have performed the following audit procedures:</p> <ul style="list-style-type: none"> <li>• obtained management's going concern position and associated forecasts and cash flow analysis;</li> <li>• assessed the reliability of forecasts to date by agreeing historical actuals to budgets, and challenging the current forecasts;</li> <li>• tested the clerical accuracy of management's forecast;</li> <li>• 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; and</li> <li>• considered the appropriateness of the Company's disclosures in relation to going concern in the financial statements.</li> </ul>	<p>We are satisfied that although there are uncertainties associated with the Company's forecasts the number of contracts in the Company's revenue pipeline mean that the Company's forecasts are reasonable and that there is not a material uncertainty in relation to going concern.</p> <p>We are also satisfied that appropriate disclosure in relation to going concern has been made in the financial statements.</p>

# Independent auditor's report continued

to the members of hVIVO plc

Risk	Our response to the risk	Key observations communicated to the Audit Committee
<p><b>Impairment of parent company investment in subsidiaries – parent company financial statements only</b></p> <p>Note 3 Critical accounting estimates and judgements (page 54); and note 3 of the parent company financial statements only (page 80).</p> <p>We identified a risk that the investment of the parent company (hVIVO plc) in its subsidiary (hVIVO Services Limited) and amounts receivable, may be impaired.</p> <p>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 impairment charges.</p>	<p>We have performed the following audit procedures:</p> <ul style="list-style-type: none"> <li>• reviewed management's assessment of indicators of impairment;</li> <li>• assessed the methodology used by management to estimate the recoverable value of the investment, in conjunction with any intra-group balances, to ensure that the method used is appropriate;</li> <li>• 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, which included: <ul style="list-style-type: none"> <li>• challenged cash inflows from revenue generating activities and the key assumptions applied in arriving at these, including the progress of research programmes; the number and value of clinical studies to be performed, and the market share of studies in key areas of disease focus;</li> <li>• assessed the reasonability of cash outflows, including contract delivery costs, and research and capital spend;</li> <li>• assessed the discount rate applied. We involved our valuations specialists to evaluate the valuation methodology and rate applied;</li> <li>• assessed the long-term growth rate;</li> </ul> </li> <li>• confirmed that any adverse change in key assumptions would not increase the impairment loss;</li> <li>• considered the appropriateness of the Company's disclosures in relation to any impairment in the Company only financial statements; and</li> <li>• ensured that disclosures of the key judgements and assumptions, and sensitivity of the impairment loss recognised was appropriately disclosed.</li> </ul>	<p>We are satisfied that management have appropriately accounted for the impairment loss recognised in accordance with accounting standards.</p> <p>We are also satisfied that the impairment is appropriately disclosed in the parent company financial statements.</p>



## An overview of the scope of our audit

### Tailoring the scope

Our assessment of audit risk, our evaluation of materiality and our allocation of performance materiality determine our audit scope for each entity within the Group. Taken together, this enables us to form an opinion on the consolidated financial statements. We take into account size, risk profile, the organisation of the Group and effectiveness of group-wide controls, changes in the business environment and other factors when assessing the level of work to be performed at each entity.

In assessing the risk of material misstatement to the Group financial statements, and to ensure we had adequate quantitative coverage of significant accounts in the financial statements, of the three reporting components of the Group, we selected all three components covering entities within the United Kingdom and United States of America, which represent the principal business units within the Group.

Of the three components selected, we performed an audit of the complete financial information of one component ("full scope component") which was selected based on their size or risk characteristics. For the remaining two components ("specific scope components"), we performed audit procedures on specific accounts within that component that we considered had the potential for the greatest impact on the significant accounts in the financial statements either because of the size of these accounts or their risk profile.

The reporting components where we performed audit procedures accounted for 100% (2017: 100%) of the Group's operating expenses, 100% (2017: 100%) of the Group's revenue and 100% (2017: 100%) of the Group's total assets. For the current year, the full scope component contributed 96% (2017: 96%) of the Group's operating expenses, 100% (2017: 100%) of the Group's revenue and 44% (2017: 44%) of the Group's total assets. The specific scope component contributed 4% (2017: 4%) of the Group's operating expenses, 0% (2017: 0%) of the Group's revenue and 56% (2017: 56%) of the Group's total assets. The audit scope of these components may not have included the testing of all significant accounts of the component but will have contributed to the coverage of significant accounts tested for the Group.

We have audited all components within the Group, and no unaudited components remain.

### Changes from the prior year

There have been no changes in our scoping from the prior year.

### Involvement with component teams

All audit work performed for the purposes of the audit was undertaken by the Group audit team.

## Our application of materiality

We apply the concept of materiality in planning and performing the audit, in evaluating the effect of identified misstatements on the audit and in forming our audit opinion.

### Materiality

The magnitude of an omission or misstatement that, individually or in the aggregate, could reasonably be expected to influence the economic decisions of the users of the financial statements. Materiality provides a basis for determining the nature and extent of our audit procedures.

We determined materiality for the Group to be £158k (2017: £343k), which is 1% (2017: 2%) of operating expenses.

We believe that operating expenses is an appropriate basis for materiality, as the Group continues in its development phase and is reporting relatively modest revenue from sales of services (relative to the level of revenue anticipated for sustained profitability) and continues to make a loss. The predominant focus of the entity is on product or service development and associated roll-out activities, which carry with it significant core infrastructure and admin costs. The Group is also incurring further research and development costs, to further develop the disease models seen as a critical success factor for the business. We have reduced the percentage of operating expenses used to determine materiality as the Group is no longer in a start-up phase.

We determined materiality for the parent company to be £865k (2017: £572k), which is 1% (2017: 0.5%) of total assets.

Materiality for the parent company only audit is greater than that of the Group. This is due to the use of total assets as a measurement basis, rather than operating expenses. We consider that total assets is an appropriate measurement basis for the parent company, as it is primarily an investment holding company with little to no stand-alone operations and activities.

During the course of our audit, we reassessed initial materiality and revised materiality due to the difference between actual measurement bases and the forecasted amounts used in determining planning materiality.

# Independent auditor's report continued

to the members of hVIVO plc

## **Our application of materiality** continued

### **Performance materiality**

The application of materiality at the individual account or balance level. It is set at an amount to reduce to an appropriately low level the probability that the aggregate of uncorrected and undetected misstatements exceeds materiality.

On the basis of our risk assessments, together with our assessment of the Group's overall control environment, our judgement was that performance materiality was 75% (2017: 75%) of our planning materiality, namely £118.5k (2017: £257k). We have set performance materiality at this percentage based on our evaluation of the past history of misstatements, our assessment that the likelihood of misstatements is limited based on our understanding of the Group, and our assessment of entity level controls.

Audit work at component locations for the purpose of obtaining audit coverage over significant financial statement accounts is undertaken based on a percentage of total performance materiality. The performance materiality set for each component is based on the relative scale and risk of the component to the Group as a whole and our assessment of the risk of misstatement at that component. In the current year, the range of performance materiality allocated to components was £24k to £101k (2017: £51k to £218k).

### **Reporting threshold**

An amount below which identified misstatements are considered as being clearly trivial.

We agreed with the Audit Committee that we would report to them all uncorrected audit differences in excess of £7.9k (2017: £13k), which is set at 5% of planning materiality, as well as differences below that threshold that, in our view, warranted reporting on qualitative grounds.

We evaluate any uncorrected misstatements against both the quantitative measures of materiality discussed above and in light of other relevant qualitative considerations in forming our opinion.

## **Other information**

The other information comprises the information included in the annual report set out on pages 1 to 34, other than the financial statements and our auditor's report thereon. The Directors are responsible for the other information.

Our opinion on the financial statements does not cover the other information and, except to the extent otherwise explicitly stated in this report, we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, 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 audit or otherwise appears to be materially misstated. If we identify such material inconsistencies or apparent material misstatements, we are required to determine whether there is a material misstatement in the financial statements or a material misstatement of the other information. If, based on the work we have performed, we conclude that there is a material misstatement of the 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 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 the parent company and its environment obtained in the course of the audit, we have not identified material misstatements in the Strategic report or the Directors' report.

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

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

### Responsibilities of Directors

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

In preparing the financial statements, the Directors are responsible for assessing the Group 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.

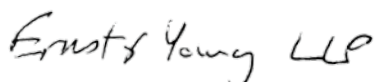
### Auditor's responsibilities for the audit of the financial statements

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.

A further description of our responsibilities for the audit of the financial statements is located on the Financial Reporting Council's website at <https://www.frc.org.uk/auditorsresponsibilities>. This description forms part of our auditor's report.

### Use of our 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.



**David Hales**

(Senior Statutory Auditor)

for and on behalf of Ernst & Young LLP  
Statutory Auditor  
Reading

11 April 2019

# Consolidated statement of comprehensive income

for the year ended 31 December 2018

	Note	2018 £'000	2017 £'000
<b>Revenue from contracts with customers</b>		<b>11,025</b>	10,878
Cost of sales		<b>(8,901)</b>	(7,316)
<b>Gross profit</b>		<b>2,124</b>	3,562
Other income	6	<b>2,601</b>	1,455
Research and development expense		<b>(4,786)</b>	(6,059)
Administrative expense		<b>(9,511)</b>	(11,379)
Impairment of intangible assets	15	<b>(2,632)</b>	—
Impairment of investment in associate	17	<b>(4,698)</b>	—
Provision against virus inventory	18	<b>(1,223)</b>	—
Loss on provision of services to joint ventures	9	—	(800)
Share of loss of associates and joint ventures	17	<b>(738)</b>	(1,613)
<b>Loss from operations</b>	7	<b>(18,863)</b>	(14,834)
Finance income	10	<b>58</b>	71
Finance costs	11	<b>(51)</b>	(54)
<b>Loss before taxation</b>		<b>(18,856)</b>	(14,817)
Taxation	12	<b>2,023</b>	1,934
<b>Loss for the year</b>		<b>(16,833)</b>	(12,883)
<b>Other comprehensive income, net of tax</b>			
Items that may be reclassified subsequently to profit or loss:			
Share of other comprehensive income of associates and joint ventures		<b>100</b>	16
Exchange differences arising on translating foreign operations		<b>9</b>	(11)
<b>Total comprehensive loss for the year attributable to owners of the parent</b>		<b>(16,724)</b>	(12,878)
Loss per share – basic (pence)	13	<b>(21.3p)</b>	(16.5p)
Loss per share – diluted (pence)	13	<b>(21.3p)</b>	(16.5p)

All activities relate to continuing operations.


The accompanying notes are an integral part of the consolidated statement of comprehensive income.

# Consolidated statement of financial position

at 31 December 2018

	Note	2018 £'000	Restated 2017 £'000
<b>Assets</b>			
<b>Non-current assets</b>			
Goodwill	14	1,722	1,722
Intangible assets	15	308	3,232
Property, plant and equipment	16	392	535
Investment in associates and joint ventures	17	7,216	12,553
		<b>9,638</b>	18,042
<b>Current assets</b>			
Inventories	18	887	1,742
Trade and other receivables	19	1,782	1,771
Contract assets	19	57	417
Research and development tax credit receivable	12	2,501	2,625
Cash and cash equivalents	20	13,368	20,289
		<b>18,595</b>	26,844
<b>Total assets</b>		<b>28,233</b>	44,886
<b>Equity and liabilities</b>			
<b>Equity</b>			
Share capital	24	4,030	3,909
Share premium account		93,434	93,290
Share-based payment reserve		779	382
Merger reserve		4,199	4,199
Other reserve		211	211
Retained deficit		(85,320)	(68,596)
<b>Total equity</b>		<b>17,333</b>	33,395
<b>Non-current liabilities</b>			
Provisions	22	20	2,280
		<b>20</b>	2,280
<b>Current liabilities</b>			
Trade and other payables	21	3,156	3,365
Contract liabilities	21	6,546	5,846
Provisions	22	1,178	—
		<b>10,880</b>	9,211
<b>Total liabilities</b>		<b>10,900</b>	11,491
<b>Total liabilities and equity</b>		<b>28,233</b>	44,886

The consolidated financial statements of hVIVO plc (registered company number 08008725) on pages 42 to 76 were approved and authorised for issue by the Board on 11 April 2019 and signed on its behalf by:



**Dr Trevor Phillips**

Executive Chairman

The accompanying notes are an integral part of the consolidated statement of financial position.

# Consolidated statement of changes in equity

for the year ended 31 December 2018

	Share capital £'000	Share premium account £'000	Share-based payment reserve £'000	Merger reserve £'000	Other reserve £'000	Retained deficit £'000	Total equity £'000
As at 31 December 2016	3,905	93,217	238	4,199	211	(55,718)	46,052
Share-based payment	—	—	144	—	—	—	144
Proceeds from shares issued:							
Issue of new shares	4	73	—	—	—	—	77
Total transactions with owners in their capacity as owners	4	73	144	—	—	—	221
Loss for the year	—	—	—	—	—	(12,883)	(12,883)
Share of other comprehensive income of associates and joint ventures	—	—	—	—	—	16	16
Exchange differences on translation of foreign assets	—	—	—	—	—	(11)	(11)
As at 31 December 2017	3,909	93,290	382	4,199	211	(68,596)	33,395
Share-based payment	—	—	454	—	—	—	454
Proceeds from shares issued:							
Issue of new shares	3	28	—	—	—	—	31
Exercise of warrants and share options	118	116	(57)	—	—	—	177
Total transactions with owners in their capacity as owners	121	144	397	—	—	—	662
Loss for the year	—	—	—	—	—	(16,833)	(16,833)
Share of other comprehensive income of associates and joint ventures	—	—	—	—	—	100	100
Exchange differences on translation of foreign assets	—	—	—	—	—	9	9
<b>As at 31 December 2018</b>	<b>4,030</b>	<b>93,434</b>	<b>779</b>	<b>4,199</b>	<b>211</b>	<b>(85,320)</b>	<b>17,333</b>

The accompanying notes are an integral part of the consolidated statement of changes in equity.

# Consolidated statement of cash flows

for the year ended 31 December 2018

	Note	2018 £'000	2017 £'000
<b>Net cash used in operating activities</b>	30	<b>(6,881)</b>	(5,065)
<b>Cash flows from investing activities</b>			
Acquisition of intangible assets		(89)	(271)
Acquisition of property, plant and equipment		(186)	(50)
Interest received		58	71
<b>Net cash used in investing activities</b>		<b>(217)</b>	(250)
<b>Cash flows from financing activities</b>			
Net proceeds from issue of shares		177	—
Other payables repaid		—	(75)
<b>Net cash generated from/(used in) financing activities</b>		<b>177</b>	(75)
<b>Net decrease in cash and cash equivalents</b>		<b>(6,921)</b>	(5,390)
Cash and cash equivalents at the start of year		20,289	25,679
<b>Cash and cash equivalents at the end of year</b>		<b>13,368</b>	20,289

The accompanying notes are an integral part of the consolidated statement of cash flows.



# Notes to the consolidated financial statements

## 1. General information

hVIVO is an industry-leading clinical development services business pioneering human disease models based upon viral challenge. Using human challenge studies to establish early proof-of-concept, hVIVO's clinical trial platform can accelerate drug and vaccine development in respiratory and infectious diseases, specifically leveraging hVIVO's established human disease challenge models in influenza ("flu"), respiratory syncytial virus ("RSV") and human rhinovirus ("HRV") and more recently the expansion and development of these models in other respiratory indications for asthma, chronic obstructive pulmonary disease ("COPD"), cough and related new therapies and in special populations. Based in the UK, hVIVO has conducted more than 50 clinical studies, inoculated over 2,700 volunteers. The Group carries out its core activities from the United Kingdom. Sales and marketing support is provided by the US-based subsidiary of the Company, hVIVO Inc.

The Company is incorporated and domiciled in the United Kingdom and its shares are listed on the London Stock Exchange's AIM market ("HVO"). The Company's registered office address is Queen Mary BioEnterprises Innovation Centre, 42 New Road, London E1 2AX, United Kingdom.

## 2. Summary of significant accounting policies

The principal accounting policies applied in the preparation of these consolidated financial statements are set out below. These policies have been consistently applied to all the years presented unless otherwise stated.

### Basis of preparation

The financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRS") as adopted by the European Union and as issued by the International Accounting Standards Board ("IASB"). The Group financial statements also comply with the requirements of the Companies Act 2006 applicable to companies reporting under IFRS.

The Company has elected to take the exemption under section 408 of the Companies Act 2006 not to present the parent company's statement of comprehensive income.

The Group financial statements are presented in Pounds Sterling and all values are rounded to the nearest thousand (£'000) except where indicated otherwise.

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

### Going concern

The Group's business activities, together with the factors likely to affect its future development, performance and position are set out in the Strategic report and Directors' report on pages 1 to 21 and pages 31 to 33.

In determining the basis for preparing the consolidated financial statements, the Directors are required to consider whether the Company can continue in operational existence for the foreseeable future, being a period of not less than twelve months from the date of the approval of the consolidated financial statements. As at 31 December 2018, the Group had cash and cash equivalents of £13.4 million (2017: £20.3 million) and net current assets of £7.7 million (2017: £17.6 million). At 31 March 2019, the Company's cash balance had reduced to £8.3 million with further outflows of £5.1 million through that date. The Company has historically been loss making given the level of research and development activity and has no borrowing facilities.

Management prepares detailed working capital forecasts which are reviewed by the Board on a regular basis. The forecasts include assumptions regarding the status of client engagements and sales pipeline, future revenues and costs together with various scenarios which reflect growth plans, opportunities, risks and mitigating actions. Management is in the process of refocussing the Company on its clinical services development business and away from its previous focus on research which increases the uncertainty of contractual forecasts.

The Company has a relatively fixed cost base which means that in order to continue to operate as a going concern it has to win and deliver sufficient contracts to cover its cost base and operate within the cash resources it has. There is inherent uncertainty in all contract forecasts which is increased because of the current stage of the Company's development. A significant proportion of 2019 financial year forecast revenue is already contracted however some of the revenue anticipated in the fourth quarter of 2019 and all of the forecast revenue for the first half of 2020 and beyond is dependent on winning and delivering new contracts.

Management has reviewed the contracts in the Company's order pipeline, discussed the likelihood of the contracts being placed with the counterparties and in the light of that assessed the likelihood of the forecast revenue being achieved. Management's forecasts indicate that the Company will continue to incur cash outflows during 2019 and in the first half of 2020 but that thereafter the Company will start to generate cash and that its current cash resources will be sufficient to enable it to continue to operate.

Although there is inherent uncertainty over the Company's forecasts and over the likelihood that the Company will win any individual contract the Directors are satisfied that there are sufficient contracts in the pipeline such that they are satisfied that sufficient revenue will be generated to allow the Company to operate within its cash resources.

Having made relevant and appropriate enquiries, including consideration of the Company's and Group's current cash resources and the working capital forecasts, the Directors have a reasonable expectation that the Company and Group will have adequate cash resources to continue to meet the requirements of the business for at least the next twelve months. Accordingly, the Board continues to adopt the going concern basis in preparing consolidated financial statements

### **Basis of consolidation**

The consolidated financial statements incorporate the financial statements of the Company and entities controlled by the Company (its subsidiaries) made up to 31 December each year. Control is achieved when the Company has the power over the investee; is exposed, or has rights, to variable return from its involvement with the investee; and, has the ability to use its power to affect its returns. The Company reassesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control listed above. Consolidation of a subsidiary begins when the Company obtains control over the subsidiary and ceases when the Company loses control of the subsidiary. Specifically, the results of subsidiaries acquired or disposed of during the year are included in the consolidated statement of comprehensive income from the date the Company gains control until the date when the Company ceases to control the subsidiary.

Where necessary, adjustments are made to the financial statements of subsidiaries to bring the accounting policies used into line with the Group's accounting policies.

All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between the members of the Group are eliminated on consolidation.

### **Business combinations**

Acquisitions of subsidiaries and businesses are accounted for using the acquisition method. The consideration transferred in a business combination is measured at fair value, which is calculated as the sum of the acquisition date fair values of assets transferred by the Group, liabilities incurred by the Group to the former owners of the acquiree and the equity interest issued by the Group in exchange for control of the acquiree. Acquisition-related costs are recognised in profit or loss as incurred.

At the acquisition date, the identifiable assets acquired and the liabilities assumed are recognised at their fair value at the acquisition date, except that:

- deferred tax assets or liabilities and assets or liabilities related to employee benefit arrangements are recognised and measured in accordance with International Accounting Standard ("IAS") 12 Income Taxes and IAS 19 Employee Benefits respectively; and
- assets (or disposal groups) that are classified as held for sale in accordance with IFRS 5 Non-current Assets Held for Sale and Discontinued Operations are measured in accordance with that Standard.

Goodwill is measured as the excess of the sum of the consideration transferred, the amount of any non-controlling interests in the acquiree, and the fair value of the acquirer's previously held equity interest in the acquiree (if any) over the net of the acquisition date amounts of the identifiable assets acquired and the liabilities assumed. If, after reassessment, the net of the acquisition date amounts of the identifiable assets acquired and liabilities assumed exceeds the sum of the consideration transferred, the amount of any non-controlling interests in the acquiree and the fair value of the acquirer's previously held interest in the acquiree (if any), the excess is recognised immediately in profit or loss as a bargain purchase gain.

When the consideration transferred by the Group in a business combination includes assets or liabilities resulting from a contingent consideration arrangement, the contingent consideration is measured at its acquisition date fair value and included as part of the consideration transferred in a business combination. Changes in fair value of the contingent consideration that qualify as measurement period adjustments are adjusted retrospectively, with corresponding adjustments against goodwill. Measurement period adjustments are adjustments that arise from additional information obtained during the 'measurement period' (which cannot exceed one year from the acquisition date) about facts and circumstances that existed at the acquisition date.

The subsequent accounting for changes in the fair value of the contingent consideration that do not qualify as measurement period adjustments depends on how the contingent consideration is classified. Contingent consideration that is classified as equity is not re-measured at subsequent reporting dates and its subsequent settlement is accounted for within equity. Contingent consideration that is classified as an asset or a liability is remeasured at subsequent reporting dates in accordance with IAS 39 Financial Instruments, or IAS 37 Provisions, Contingent Liabilities and Contingent Assets, as appropriate, with the corresponding gain or loss being recognised in profit or loss.

# Notes to the consolidated financial statements continued

## 2. Summary of significant accounting policies continued

### Business combinations continued

When a business combination is achieved in stages, the Group's previously-held interests in the acquired entity is remeasured to its acquisition date fair value and the resulting gain or loss, if any, is recognised in profit or loss. Amounts arising from interests in the acquiree prior to the acquisition date that have previously been recognised in other comprehensive income are reclassified to profit or loss, where such treatment would be appropriate if that interest were disposed of.

If the initial accounting for a business combination is incomplete by the end of the reporting period in which the combination occurs, the Group reports provisional amounts for the items for which the accounting is incomplete. Those provisional amounts are adjusted during the measurement period (see above), or additional assets or liabilities are recognised, to reflect new information obtained about facts and circumstances that existed as of the acquisition date that, if known, would have affected the amounts recognised as of that date.

### Investment in associates and joint ventures

An associate is an entity over which the Group has significant influence and that is neither a subsidiary nor an interest in a joint venture. Significant influence is the power to participate in the financial and operating policy decisions of the investee but is not control or joint control over those policies.

A joint venture is a joint arrangement whereby parties that have joint control of the arrangement have rights to the net assets of the arrangement.

The results and assets and liabilities of associates and joint ventures are incorporated in these financial statements using the equity method of accounting. Under the equity method, an investment in an associate or joint venture is initially recognised in the consolidated statement of financial position at cost and adjusted thereafter to recognise the Group's share of profit or loss and other comprehensive income of the associate or joint venture. When the Group's share of losses of an associate or joint venture exceeds the Group's interest in that associate or joint venture, the Group discontinues recognising its share of further losses. Additional losses are recognised only to the extent that the Group has incurred a legal or constructive obligation or made payments on behalf of the associate or joint venture. hVIVO recognises revenues arising from transactions with associates and joint ventures in its consolidated financial statements.

An investment in an associate or joint venture is accounted for using the equity method from the date on which the investee becomes an associate or joint venture. On acquisition of the investment in an associate or a joint venture, any excess of the cost of the investment over the Group's share of the net fair value of the identifiable assets and liabilities of the investee is recognised as goodwill, which is included within the carrying amount of investment.

The requirements of IAS 28 are applied to determine whether it is necessary to recognise any impairment loss with respect to the Group's investment in an associate or joint venture. When necessary, the entire carrying amount of the investment (including goodwill), is tested for impairment in accordance with IAS 36 Impairment of Assets as a single asset by comparing its recoverable amount (higher of value in use and fair value less costs of disposal) with its carrying amount. Any impairment loss recognised forms part of the carrying amount of the investment. Any reversal of that impairment loss is recognised in accordance with IAS 36 to the extent that the recoverable amount of the investment subsequently increases.

The Group discontinues the use of the equity method from the date when the investment ceases to be an associate or joint venture, or when the investment is classified as held for sale.

### Foreign currencies

The individual financial statements of each Group company are presented in the currency of the primary economic environment in which it operates (its functional currency). For the purpose of the consolidated financial statements, the results and financial position of each Group company are expressed in Pounds Sterling, which is the functional currency of the Company, and the presentation currency for the consolidated financial statements.

In preparing the financial statements of the individual companies, transactions in currencies other than the entity's functional currency (foreign currencies) are recognised at the rates of exchange prevailing at the date of transaction. Non-monetary items carried at fair value that are denominated in foreign currencies are translated at the rates prevailing at the date when fair value was determined. Non-monetary items that are measured in terms of historical cost in a foreign currency are not retranslated.

For the purpose of presenting consolidated financial statements, the assets and liabilities of the Group's foreign operations are translated at exchange rates prevailing on the balance sheet date. Income and expense items are translated at the average exchange rates for the period unless exchange rates fluctuate significantly during that period, in which case the exchange rates at the date of transactions are used. Exchange differences arising, if any, are recognised in other comprehensive income and accumulated in equity.

## Revenue recognition

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

### Service revenues

The Group primarily earns revenues by undertaking customer clinical services engagements. A customer 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 customer 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.

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

The Group 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 customer 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 Group 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 consolidated 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 Group to be paid for all work performed to the termination date (enforceable right to payment for services provided to date).

### Licencing revenues

Where licencing 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 Group 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 consolidated 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 licencing 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.

# Notes to the consolidated financial statements continued

## 2. Summary of significant accounting policies continued

### Government grants

Government grants are recognised when there is reasonable assurance that the grant will be received and all attached conditions will be complied with. When the grant relates to an expense item, it is recognised as income on a systematic basis over the periods that the related costs, for which it is intended to compensate, are expensed. When the grant relates to an asset, it is recognised as income in equal amounts over the expected useful life of the asset.

### Internally generated intangible assets – 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.

### Intangible assets

The cost of a purchased intangible asset is the purchase price plus any cost directly attributable to bringing the asset to the location and condition necessary for it to be capable of operating in the manner intended. Intangible assets acquired in a business combination and recognised separately from goodwill are recognised at their fair value at the acquisition date (which is regarded as their cost). Intangible assets are reported at cost less accumulated amortisation and accumulated impairment losses. Amortisation is recognised on a straight-line basis over their estimated useful lives. The estimated life and the amortisation method for each intangible asset are reviewed at the end of each reporting period, with the effect of any changes in estimate being accounted for on a prospective basis. The useful lives of assets for amortisation range from five to ten years.

### Property, plant and equipment

Property, plant and equipment is stated at cost less accumulated depreciation and any impairment losses. Cost includes expenditure that is directly attributable to the acquisition of the items. Subsequent costs are included in the asset's carrying amount or recognised as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Group and the cost of the item can be measured reliably. All repairs and maintenance costs are charged to the consolidated statement of comprehensive income during the period in which they are incurred.

Depreciation is charged, on a straight-line basis, so as to write off the costs of assets less their residual values, over their estimated useful lives, on the following basis:

Leasehold improvements	the shorter of five years or the life of the lease
Plant and machinery	four years straight line
Computer equipment	three years straight line

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

The gain or loss arising on the disposal of an asset is determined as the difference between the sales proceeds and the carrying amount of the asset and is recognised in the consolidated statement of comprehensive income.

### Impairment of tangible and intangible assets

At each reporting date, the Group reviews the carrying amounts of its tangible and intangible assets to determine whether there is any indication that those assets have suffered an impairment loss. If any such indication exists, the recoverable amount of the asset is estimated in order to determine the extent of the impairment loss (if any). Where the asset does not generate cash flows that are independent of other assets, the Group estimates the recoverable amount of the cash generating unit to which the asset belongs.

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

If the recoverable amount of an asset (or cash generating unit) is estimated to be less than its carrying amount, the carrying amount of the asset (or cash generating unit) is reduced to its recoverable amount. An impairment loss is recognised as an expense immediately.

### Impairment of goodwill

Goodwill is not amortised but is reviewed for impairment at each reporting date. For the purposes of impairment testing, goodwill is allocated to each of the Group's cash generating units expected to benefit from the synergies of the combination. Cash generating units to which goodwill has been allocated are tested for impairment at each reporting date, or more frequently when there is an indication that the unit may be impaired. If the recoverable amount of the cash generating unit is less than the carrying amount of the unit, the impairment loss is allocated first to reduce the carrying amount of any goodwill allocated to the unit and then to the other assets of the unit pro-rata on the basis of the carrying amount of each asset in the unit. An impairment loss recognised for goodwill is not reversed in a subsequent period.

### 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 the 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 consolidated statement of comprehensive income.

### Financial instruments

Financial assets and financial liabilities are recognised in the consolidated statement of financial position when the Group becomes party to the contractual provisions of the instrument. Financial assets are derecognised when the contractual rights to the cash flows from the financial asset expire or when the contractual rights to those assets are transferred. Financial liabilities are derecognised when the obligation specified in the contract is discharged, cancelled or expired.

### Trade receivables

Trade receivables are amounts due from customers for goods sold or services performed in the ordinary course of business. Trade receivables are recognised initially at fair value and subsequently measured at amortised cost using the effective interest method, less provision for impairment. Appropriate provisions for estimated irrecoverable amounts are recognised in the consolidated statement of comprehensive income using the expected credit loss method. The carrying amount of these assets approximates their fair value.

### Cash and cash equivalents

Cash and cash equivalents comprise cash in hand, demand deposits, and other short-term highly liquid investments that are readily convertible to a known amount of cash and are subject to an insignificant risk of changes in value. The carrying amount of these assets approximates their fair value.

### Short-term deposits

Short-term deposits comprise money market deposits which are convertible to known amounts of cash and have an original maturity of between three and twelve months.

# Notes to the consolidated financial statements continued

## 2. Summary of significant accounting policies continued

### Financial instruments continued

#### Equity instruments

An equity instrument is any contract that evidences a residual interest in the assets of an entity after deducting all of its liabilities. Equity instruments issued by the Group are recorded at the proceeds received net of direct issue costs.

#### Trade and other payables

Trade payables are obligations to pay for goods or services that have been acquired in the ordinary course of business from suppliers. Trade payables are recognised initially at their fair value and are subsequently measured at their amortised cost using the effective interest rate method. Due to the short-term nature of these balances, the carrying amount of trade payables approximates to their fair value.

#### Borrowings

Borrowings, including advances received from related parties, are initially recognised at the fair value of the consideration received less directly attributable transaction costs. After initial recognition borrowings are subsequently measured at amortised cost using the effective interest method.

#### Current and deferred tax

The tax credit recognised within the consolidated statement of comprehensive income represents the sum of the taxes currently payable or recoverable and the movements in deferred tax assets and liabilities.

The tax currently payable is based on taxable profit or loss for the year. Taxable profit or loss differs from net profit or loss before income tax as reported in the consolidated statement of comprehensive income because it excludes items of income or expense that are taxable or deductible in other years and it further excludes items that are never taxable or deductible. The Group's liability for current tax is calculated by using tax rates that have been enacted or substantively enacted by the reporting date.

Credit is taken in the accounting period for research and development tax credits, which will be claimed from HM Revenue & Customs, in respect of qualifying research and development costs incurred in the same accounting period.

Deferred tax is the tax expected to be payable or recoverable on differences between the carrying amounts of assets and liabilities in the financial statements and the corresponding tax bases used in the computation of taxable profit, and is accounted for using the liability method. Deferred tax liabilities are generally recognised for all taxable temporary differences and deferred tax assets are recognised to the extent that it is probable that taxable profits will be available against which deductible temporary differences can be utilised. Such assets and liabilities are not recognised if the temporary difference arises from goodwill or from the initial recognition (other than in a business combination) of other assets and liabilities in a transaction that affects neither the tax profit nor the accounting profit.

Deferred tax liabilities are recognised for taxable temporary differences arising on investments in subsidiaries and associates, and interests in joint ventures, except where the Group is able to control the reversal of the temporary difference and it is probable that the temporary difference will not reverse in the foreseeable future. Deferred tax assets arising from deductible temporary differences associated with such investments and interests are only recognised to the extent that it is probable that there will be sufficient taxable profits against which to utilise the benefits of the temporary differences and they are expected to reverse in the foreseeable future.

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

The measurement of deferred tax liabilities and assets reflects the tax consequences that would follow from the manner in which the Group expects, at the end of the reporting period, to recover or settle the carrying amount of its assets and liabilities.

Deferred tax assets and liabilities are offset when there is a legally enforceable right to set off current tax assets against current tax liabilities and when they relate to income taxes levied by the same taxation authority and the Group intends to settle its current tax assets and liabilities on a net basis.

Deferred tax is calculated at the tax rates that are expected to apply to the period when the asset is realised or the liability is settled based upon tax rates that have been enacted or substantively enacted by the reporting date. Deferred tax is charged or credited in the consolidated statement of comprehensive income, except when it relates to items credited or charged directly to equity, in which case the deferred tax is also dealt with in equity.



Where current tax or deferred tax arises from the initial accounting for a business combination, the tax effect is included in the accounting for the business combination.

Research and Development Expenditure Credits to be received in cash are recorded in other income in the period in which the qualifying expenditure was incurred, once the underlying claim methodology has been agreed with HM Revenue & Customs.

### Operating leases

The determination of whether an arrangement is a lease is based on the substance of the arrangement at the inception of the lease. The arrangement is a lease if fulfilment of the arrangement is dependent on the use of a specific asset and the arrangement conveys a right to use the asset, even if that asset is not explicitly specified in an arrangement.

Rentals payable under operating leases are charged to expense on a straight-line basis over the term of the relevant lease. Contingent rentals arising under operating leases are recognised as an expense in the period in which they are incurred.

In the event that lease incentives are received to enter into operating leases, such incentives are recognised as a liability. The aggregate benefit of incentives is recognised as a reduction of rental expense on a straight-line basis over the lease term, except where another systematic basis is more representative of the time pattern in which economic benefits from the leased asset are consumed.

### Share-based payment transactions

#### Options

The Group operates an equity-settled share-based compensation plan, under which the Group receives services from employees (including Directors) as consideration for equity instruments (options) of the Company. The fair value of the employee services received in exchange for the grant of the options is recognised as an expense over the vesting period.

The total amount to be expensed is determined by reference to the fair value of the options granted at the grant date. The fair value excludes the effect of non-market-based vesting conditions. Details regarding the determination of the fair value of equity-settled share-based transactions are set out in note 25.

The fair value determined at the date of grant is expensed on a straight-line basis over the vesting period, based upon the Group's estimate of the number of equity instruments that will eventually vest. At each reporting date, the Group revises its estimate of the number of equity instruments expected to vest as a result of the effect of non-market-based vesting conditions. The impact of the revision of the original estimates, if any, is recognised in profit or loss such that the cumulative expense reflects the revised estimate, with a corresponding adjustment to equity reserves.

#### Warrants

The Group enters into equity-settled share-based payment transactions, involving the issuance of warrants, with parties other than employees. Pursuant to these transactions, the Group receives services from such parties as consideration for equity instruments (warrants) issued. The fair value of such services received in exchange for the grant of warrants is recognised as an expense over the service period.

### Pension costs

The Group operates a defined contribution pension scheme for all employees. The assets of the scheme are held separately from those of the Group. Payments into the scheme are charged as an expense as they fall due.

### Provisions

Provisions for dilapidations and onerous lease commitments are recognised when:

- the Group has a present legal or constructive obligation as a result of past events;
- it is probable that the Group will be required to settle that obligation; and
- a reliable estimate can be made of the amount of the obligation.

The amount recognised as a provision is the best estimate 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. Where a provision is measured using the cash flows estimated to settle the present obligation, its carrying amount is the present value of those cash flows (when the effect of the time value of money is material). When some or all of the economic benefits required to settle a provision are expected to be recovered from a third party, a receivable is recognised as an asset if it is virtually certain that reimbursement will be received and the amount of the receivable can be measured reliably.

# Notes to the consolidated financial statements continued

## 3. Critical accounting estimates and judgements

In the application of the Group's accounting policies, which are described in note 2, the Group makes estimates and assumptions concerning the future based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates. The estimates and underlying assumptions are reviewed on an ongoing basis. The estimates and assumptions that have a significant effect on the amounts recognised in the financial statements are addressed below.

### Revenue from contracts with customers, contract assets and contract liabilities

Revenue from contracts with customers for the performance of services is recognised over time based on the level of work completed. The recognition of revenue from contracts with customers (and hence the related contract asset and contract liability balances) requires management to make estimates in relation to the level of work done and assumptions of the costs to complete each project.

At each period end, management reviews each 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.

### Revenue from transactions with related parties, associates and joint ventures

The recognition and presentation of revenue generating transactions as at an arm's-length require management to make judgements on the fair value of the consideration received and whether the transactions have stand-alone commercial substance.

hVIVO recognised revenue from transactions with related parties of £0.03 million during the year (2017: £2.9 million), of which PrEP Biopharm Limited £0.03 million (2017: £0.3 million) and PepTcell Limited £nil (2017: £2.6 million).

Management has concluded that these transactions were at an arm's-length fair value (see note 27).

### Impairment of intangible assets, investments and goodwill

The Group's balance sheet includes goodwill, investments and intangible assets. Impairment exists when the carrying value of an asset or cash generating unit exceeds its recoverable amount, which is the higher of fair value less costs of disposal and its value in use. Determining whether an asset is impaired requires estimation of the fair value of the asset or cash generating unit or the estimation of the value in use of the cash generating unit to which the asset has been allocated. Management has determined an impairment of intangible assets of £2.6 million is required (see note 15). This was a change in estimate from the Group's condensed consolidated interim financial statements prepared for the six months ended 30 June 2018.

### 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. Due to a reforecast of the future commercial usage of Perth virus, management has determined a provision of £1.2 million is required (see note 18). This was a change in estimate from the Group's condensed consolidated interim financial statements prepared for the six months ended 30 June 2018.

### Investments in associates and joint ventures

In assessing the level of control hVIVO holds in respect of its equity investments, management considers a number of factors including control of voting rights at board level and the power to direct the "relevant activities" of that investee through decision making and the management of assets.

The differences between consolidating a controlled entity and applying the equity method are significant. The equity method requires hVIVO to recognise its share of profits and losses and other changes in the net assets of the associates and joint ventures.

### PrEP Biopharm Limited

On 1 November 2015, the Company acquired 62.62% of the share capital of PrEP Biopharm Limited. Although hVIVO holds more than 50% of the equity of PrEP Biopharm Limited, hVIVO's voting rights are limited to 49.98% under the Investment and Shareholders' Agreement ("ISHA"). The effect is that the voting rights hVIVO is entitled to exercise are less than half of the total voting rights that are able to be exercised.

Under the terms of the ISHA, hVIVO has appointed two Directors of PrEP Biopharm Limited, including the Chair, with equal votes and no casting vote. There are currently five Directors, following the appointment of an independent Non-Executive Director in August 2016. Accordingly, hVIVO does not control the Board.

The terms of the ISHA exclude the hVIVO Directors from any Board consideration and decision making on the hVIVO contracts. Under the terms of the PrEP Biopharm Limited transaction, PrEP Biopharm Limited contracted with hVIVO Services Limited for the licence of PrEP-001 flu and PrEP-001 asthma clinical study data and also to conduct a PrEP-001 durability clinical study under a client services agreement, for a total consideration of £10.0 million. The hVIVO contracts with PrEP Biopharm Limited were priced on an arm's-length basis.

Management has concluded that despite having significant influence, the terms of the ISHA mean that it does not have the power to direct the relevant activities of PrEP Biopharm Limited. Accordingly, hVIVO uses the equity method to account for its investment in PrEP Biopharm Limited as an associate. The activity of PrEP Biopharm Limited is that of clinical research.

### Imutex Limited

On 21 April 2016, the Company acquired 49.0% of the share capital of Imutex Limited under the terms of a Joint Venture Agreement with PepTcell Limited. hVIVO holds 49.0% of the voting rights of Imutex Limited and, under the terms of the Joint Venture Agreement, appoints two of the current four Directors.

Management has concluded that the relevant activities of Imutex Limited are jointly controlled by PepTcell Limited and hVIVO. Accordingly, hVIVO uses the equity method to account for its investment in Imutex Limited as a joint venture with joint control. The activity of Imutex Limited is that of clinical research.

### Impairment of investments in associates and joint ventures

Management has assessed whether there are any indicators that the carrying amount of investments in associates and joint ventures may be impaired. In performing this assessment, management has considered the progress of the early stage clinical research programmes being conducted by the associates and joint ventures. Management has performed an impairment assessment and determined that an impairment of the carrying amount of the investment in PrEP Biopharm Limited is required (see note 17).

### 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.

### Research and development tax credit

The Group's research and development tax claim is complex and requires management to make significant assumptions in building the methodology for the claim, interpreting research and development tax legislation to the Group's specific circumstances, and agreeing the basis of the Group's tax computations with HM Revenue & Customs.

## Notes to the consolidated financial statements continued

### 4. Interpretations of accounting standards

#### Amendments to published standards effective for the year ended 31 December 2018

The Group has not early adopted any standards, interpretations or amendments.

The Group applies, for the first time, IFRS 15 Revenue from Contracts with Customers and IFRS 9 Financial Instruments that require restatement of previous financial statements. As required by IAS 34, the nature and effect of these changes are disclosed below.

Several other amendments and interpretations apply for the first time in 2018, but do not have an impact on the Consolidated Financial Statements of the Group.

#### a. IFRS 15 Revenue from Contracts with Customers

IFRS 15 supersedes IAS 11 Construction Contracts, IAS 18 Revenue and related Interpretations and it applies to all revenue arising from contracts with customers unless those contracts are in the scope of other standards. The new standard establishes a five-step model to account for revenue arising from contracts with customers. Under IFRS 15, revenue is recognised at an amount that reflects the consideration to which an entity expects to be entitled in exchange for transferring goods or services to a customer.

The standard requires entities to exercise judgement, taking into consideration all of the relevant facts and circumstances when applying each step of the model to contracts with their customers. The standard also specifies the accounting for the incremental costs of obtaining a contract and the costs directly related to fulfilling a contract.

The Group adopted IFRS 15 using the full retrospective method of adoption in accordance with IFRS 15 transitional provisions. The effect of this is as follows:

#### Impact on the statement of financial position (increase/(decrease))

	Year ended 31 Dec 2018 £'000	Year ended 31 Dec 2017 £'000
<b>Assets</b>		
Trade and other receivables	(57)	(417)
Contract assets	57	417
<b>Total assets</b>	—	—
<b>Liabilities</b>		
Trade and other payables	(6,546)	(5,846)
Contract liabilities	6,546	5,846
<b>Total liabilities</b>	—	—

#### Service revenues

Prior to the adoption of IFRS 15, the Group recognised client clinical services revenue on a percentage of completion method using output measures. Depending on the contractual terms, revenue was recognised based on the level of work completed to date in respect of each individual element of the client clinical services contract.

Under IFRS 15, the Group concluded that revenue from client clinical services will continue to be recognised over time, using an output method to measure progress towards complete satisfaction of the service similar to the previous accounting policy, because the Group has an enforceable right to payment for completion of services to date. Moreover, under IFRS 15, any earned consideration that is conditional should be recognised as a contract asset rather than receivable. Therefore, upon adoption of IFRS 15, the Group made reclassifications from trade and other receivables to contract assets.

The statement of financial position as at 31 December 2017 was restated, resulting in recognition of contract assets amounting to £417,000, and decrease in trade and other receivables amounting to £417,000.

### Advances received from customers

Generally, the Group receives short-term advances from its customers. Upon the adoption of IFRS 15, for short-term advances, the Group used the practical expedient. As such, the Group will not adjust the promised amount of the consideration for the effects of a financing component in contracts, where the Group expects, at contract inception, that the period between the time the customer pays for the good or service and when the Group transfers that promised good or service to the customer will be one year or less.

Reclassifications have been made from deferred revenue to contract liabilities for the outstanding balance of advances from customers. The statement of financial position as at 31 December 2017 was restated, resulting in: increases in current and non-current portions of contract liabilities amounting to £5,846,000 and £nil, respectively; decreases in current and non-current portions of deferred revenue amounting to £5,846,000, and £nil, respectively; and decrease in retained earnings amounting to £nil.

### Presentation and disclosure requirements

As required for the consolidated financial statements, the Group disaggregated revenue recognised from contracts with customers into categories that depict how the nature, amount, timing and uncertainty of revenue and cash flows are affected by economic factors. The Group also disclosed information about the relationship between the disclosure of disaggregated revenue and revenue information disclosed for each reportable segment. Refer to note 3 for the disclosure on disaggregated revenue. The application of IFRS 15 has not had any impact on the amount of basic or diluted earnings per share (note 13).

## b. IFRS 9 Financial Instruments

IFRS 9 Financial Instruments replaces IAS 39 Financial Instruments: Recognition and Measurement for annual periods beginning on or after 1 January 2018, bringing together all three aspects of the accounting for financial instruments: classification and measurement; impairment; and hedge accounting.

The Group has applied IFRS 9 in full without restating comparatives with an initial date of application of 1 January 2018. Management has determined that the impact on the Group in relation to the application of this policy is not material.

### Classification and measurement

Except for certain trade receivables, under IFRS 9, 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.

Under IFRS 9, debt financial instruments are subsequently measured at fair value through profit or loss ("FVPL"), amortised cost, or fair value through other comprehensive income ("FVOCI"). The classification is based on two criteria: the Group's business model for managing the assets; and whether the instruments' contractual cash flows represent 'solely payments of principal and interest' on the principal amount outstanding (the "SPPI criterion").

The new classification and measurement of the Group's debt financial assets is as follows:

- debt instruments at amortised cost for financial assets that are held within a business model with the objective to hold the financial assets in order to collect contractual cash flows that meet the SPPI criterion. This category includes the Group's Trade and other receivables, and Loans included under other current financial assets.

The assessment of the Group's business models was made as of the date of initial application, 1 January 2018. The assessment of whether contractual cash flows on debt instruments are solely comprised of principal and interest was made based on the facts and circumstances as at the initial recognition of the assets.

The accounting for the Group's financial liabilities remains largely the same as it was under IAS 39. Similar to the requirements of IAS 39, IFRS 9 requires contingent consideration liabilities to be treated as financial instruments measured at fair value, with the changes in fair value recognised in the statement of profit or loss. Under IFRS 9, embedded derivatives are no longer separated from a host financial asset. Instead, financial assets are classified based on their contractual terms and the Group's business model. The accounting for derivatives embedded in financial liabilities and in non-financial host contracts has not changed from that required by IAS 39.

# Notes to the consolidated financial statements continued

## 4. Interpretations of accounting standards continued

### b. IFRS 9 Financial Instruments continued

#### Impairment

The adoption of IFRS 9 has fundamentally changed the Group's accounting for impairment losses for financial assets by replacing IAS 39's incurred loss approach with a forward-looking expected credit loss ("ECL") approach.

IFRS 9 requires the Group to record an allowance for ECLs for all loans and other debt financial assets not held at FVPL.

ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all the cash flows that the Group expects to receive. The shortfall is then discounted at an approximation to the asset's original effective interest rate.

For contract assets and trade and other receivables, the Group has applied the standard's simplified approach and has calculated ECLs based on lifetime expected credit losses. The Group has established a provision matrix that is based on the Group's historical credit loss experience, adjusted for forward-looking factors specific to the debtors and the economic environment.

The Group considers a financial asset in default when contractual payment is 90 days past due. However, in certain cases, the Group may also consider a financial asset to be in default when internal or external information indicates that the Group is unlikely to receive the outstanding contractual amounts in full before taking into account any credit enhancements held by the Group.

The adoption of the ECL requirements of IFRS 9 did not result in any increases in impairment allowances of the Group's debt financial assets, as management's assessment of the ECLs have indicated that these are not material.

### c. IFRIC Interpretation 22 Foreign Currency Transactions and Advance Considerations

The Interpretation clarifies that, in determining the spot exchange rate to use on initial recognition of the related asset, expense or income (or part of it) on the derecognition of a non-monetary asset or non-monetary liability relating to advance consideration, the date of the transaction is the date on which an entity initially recognises the non-monetary asset or non-monetary liability arising from the advance consideration. This Interpretation does not have any impact on the Group's consolidated financial statements.

### d. Amendments to IFRS 2 Classification and Measurement of Share-based Payment Transactions

The IASB issued amendments to IFRS 2 Share-based Payment that address three main areas: the effects of vesting conditions on the measurement of a cash-settled share-based payment transaction; the classification of a share-based payment transaction with net settlement features for withholding tax obligations; and accounting where a modification to the terms and conditions of a share-based payment transaction changes its classification from cash settled to equity settled. The Group has no cash-settled share-based payment arrangements. Therefore, these amendments do not have any impact on the Group's consolidated financial statements.

### Standards adopted early by the Group

The Group has not adopted any standards or interpretations early in either the current or preceding financial year.

### New and revised IFRS in issue but not yet effective

Interpretations to existing standards and new standards that are not yet effective and have not been early adopted by the Group:

- IFRS 16 Leases (effective date 1 January 2019);
- IFRS 17 Insurance Contracts (effective date 1 January 2021);
- IFRIC 23 Uncertainty over Income Tax Treatments (effective date 1 January 2019).

The Directors are of the opinion that the application of these standards is unlikely to have a significant impact on the financial statements of the Group or Company.

### IFRS 16 Leases

IFRS 16 was issued in January 2016 and it replaces IAS 17 Leases, IFRIC 4 Determining whether an arrangement contains a Lease, SIC-15 Operating Leases-Incentives and SIC-27 Evaluating the Substance of Transactions Involving the Legal Form of a Lease. IFRS 16 sets out the principles for the recognition, measurement, presentation and disclosure of leases and requires lessees to account for all leases under a single on-balance sheet model similar to the accounting for finance leases under IAS 17. The standard includes two recognition exemptions for lessees – leases of 'low-value' assets (e.g. personal computers) and short-term leases (i.e. leases with a lease term of twelve months or less). At the commencement date of a lease, a lessee will recognise a liability to make lease payments (i.e. the lease liability) and an asset representing the right to use the underlying asset during the lease term (i.e. the right-of-use asset).

Lessees will be required to separately recognise the interest expense on the lease liability and the depreciation expense on the right-of-use asset.

Lessees will be also required to remeasure the lease liability upon the occurrence of certain events (e.g., a change in the lease term, a change in future lease payments resulting from a change in an index or rate used to determine those payments). The lessee will generally recognise the amount of the remeasurement of the lease liability as an adjustment to the right-of-use asset.

IFRS 16, which is effective for annual periods beginning on or after 1 January 2019, requires lessees and lessors to make more extensive disclosures than under IAS 17.

### Transition to IFRS 16

The Group intends to apply the simplified transition approach and will not restate comparative amounts for the year prior to first adoption. The Group will elect to apply the standard to contracts that were previously identified as leases applying IAS 17 and IFRIC 4. The Group will therefore not apply the standard to contracts that were not previously identified as containing a lease applying IAS 17 and IFRIC 4.

The Group will elect to use the exemptions proposed by the standard on lease contracts for which the lease terms end within twelve months as of the date of initial application, and lease contracts for which the underlying asset is of low value. The Group has leases of certain office equipment (i.e. printing and photocopying machines) that are considered of low value.

During 2018, the Group has performed a detailed impact assessment of IFRS 16. In summary, the impact of IFRS 16 adoption is expected to be, as follows:

### Impact on the consolidated statement of financial position as at 31 December 2018:

	31 December 2018 £'000
<b>Assets:</b>	
Property, plant and equipment (right-of-use assets)	200
Prepayments	(18)
<b>Liabilities:</b>	
Lease liabilities	(239)
<b>Net impact on equity</b>	<b>57</b>

The impact in the consolidated statement of comprehensive income in 2019 is an increase in finance cost of £11,000 and an increase to depreciation of £52,000.



# Notes to the consolidated financial statements continued

## 5. Segmental information and revenue from contracts with customers

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

Kym Denny stepped down as Chief Executive Officer on 18 April 2018 and Trevor Phillips, the Executive Chairman, has taken over her responsibilities.

The Group carries out its main activities from the United Kingdom. The Group conducts sales activity in the US and in Europe which is carried out through hVIVO Inc and hVIVO Services Limited respectively. All revenue from contracts with customers is derived from activities undertaken in the UK.

During the year ended 31 December 2018, the Group had four customers who each generated revenue greater than 10% of total revenue (2017: three customers). These customers generated 36%, 25%, 17% and 16% of revenue (2017: 44%, 24% and 15% of revenue).

£5.6 million of revenue from contracts with customers (2017: £3.1 million) recognised during the year was included in the opening balance of contract liabilities. The value of contract liabilities has increased from £5.8 million at 31 December 2017 to £6.5 million at 31 December 2018 due to the signing of a number of new projects during the year. Contract assets have decreased from £0.4 million at 31 December 2017 to £0.06 million at 31 December 2018 predominantly due to the completion of a project during 2018 that was in progress as at 31 December 2017.

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 2018 £'000	31 December 2017 £'000
Within six months	6,262	4,345
Between six months and one year	26	1,243
After one year	258	258
	<b>6,546</b>	<b>5,846</b>

Generally, 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 with 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 the date of invoice.

The Group considers whether there are other promises in the contract that are separate performance obligations to which a portion of the transaction price needs to be allocated. The Group'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 Group 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.

## 6. Other income

Other income includes £2.3 million (2017: £1.3 million) of public health cost-share grant awarded by US Defense Advanced Research Projects Agency ("DARPA") for a flu contagiousness R&D project and £0.3 million (2017: £0.1 million) accrued in respect of a Research and Development Expenditure Credit ("RDEC") claim for 2018. The Group classifies such RDEC claims as a government grant where amounts receivable as compensation for expenses or losses already incurred are recognised in the consolidated statement of comprehensive income in the period in which they become receivable.

## 7. Loss from operations

Loss before tax is stated after charging:

	Year ended 31 December 2018 £'000	Year ended 31 December 2017 £'000
Employee benefit expense (note 8)	10,902	11,525
Recruitment and other human resources	155	151
Agency and interim consultants	2,837	2,587
Premises and equipment	2,493	2,065
Volunteer costs	1,901	1,499
Inventories used	863	832
Virus inventory provision (note 18)	1,223	(6)
Insurance	197	212
Professional fees	1,462	1,599
Information technology, including telecommunications	698	672
Gain on forward contracts	—	(10)
(Gain)/loss on foreign exchange	(210)	57
Depreciation of property, plant and equipment	329	1,068
Amortisation and impairment of intangible assets (note 15)	3,013	414
Impairment of investment in associate (note 17)	4,698	—
Dilapidations and onerous lease expense (note 22)	13	611

Amounts payable to the Company's external auditor and its associates were as follows:

	Year ended 31 December 2018 £'000	Year ended 31 December 2017 £'000
<b>Auditor fee:</b>		
Fees payable to the Company's auditor for the audit of the Company's annual financial statements	70	50
Fees payable to the Company's auditor and its associates for other services		
– the audit of the Company's subsidiaries pursuant to legislation	70	50
<b>Total audit fees</b>	<b>140</b>	<b>100</b>
Audit-related fees – audit-related assurance services	20	20
<b>Total audit and audit-related fees</b>	<b>160</b>	<b>120</b>
All other fees – other services	26	56
<b>Total non-audit fees</b>	<b>26</b>	<b>56</b>
	<b>186</b>	<b>176</b>

# Notes to the consolidated financial statements continued

## 8. Employees

	Year ended 31 December 2018 Number	Year ended 31 December 2017 Number
The average number of FTE employees (including Executive Directors) was:		
Management, administration and business development	40	45
hVIVO platform operation	86	105
Discovery and innovation	12	14
	<b>138</b>	<b>164</b>

In addition to the above, the Company employed one FTE employee (2017: four) absent for maternity leave, paternity leave and long-term sickness.

	Year ended 31 December 2018 £'000	Year ended 31 December 2017 £'000
The aggregate employee benefit expense comprised (including Directors):		
Wages and salaries	9,073	9,913
Social security costs	981	1,006
Pension cost – defined contribution plans	394	462
Share option expense	454	144
	<b>10,902</b>	<b>11,525</b>

The remuneration of the Executive Directors, who are the key management personnel of the Group, is shown within note 27.

## 9. Loss on provision of services to joint ventures

	Year ended 31 December 2018 £'000	Year ended 31 December 2017 £'000
Loss on provision of services to joint ventures	—	800

hVIVO Services Limited agreed in 2016 a £1.0 million change in the scope of the FLU-v study, increasing the number of volunteers in the study to power the primary and a selection of secondary endpoints. This was funded by hVIVO plc purchasing from Imutex Limited a right to future royalty upon the achievement of certain milestones (see note 3 to the Company financial statements). The income from the scope change was not recognised in the consolidated statement of comprehensive income as it was entirely funded by hVIVO. The quarantines for the FLU-v study completed during 2017 and the associated costs of the scope change, together with subsequent analysis of study data, were recognised as a loss on provision of services to joint ventures. There have been no equivalent costs or income during 2018.

## 10. Finance income

	Year ended 31 December 2018 £'000	Year ended 31 December 2017 £'000
Interest received	58	71

## 11. Finance costs

	Year ended 31 December 2018 £'000	Year ended 31 December 2017 £'000
Other bank charges	10	13
Other finance costs	41	41
	<b>51</b>	<b>54</b>

## 12. Taxation

	Year ended 31 December 2018 £'000	Year ended 31 December 2017 £'000
Current tax:		
Current year research and development tax credit	(2,043)	(2,261)
Adjustments in respect of previous periods	5	285
Foreign current tax	15	42
	<b>(2,023)</b>	<b>(1,934)</b>

Corporation tax is calculated at 19% (2017: 19.25%) of the estimated taxable loss for the year.

The charge for the year can be reconciled to the loss in the consolidated statement of comprehensive income as follows:

	Year ended 31 December 2018 £'000	Year ended 31 December 2017 £'000
Loss before taxation	(18,856)	(14,817)
Tax at the UK corporation tax rate of 19% (2017: 19.25%)	(3,583)	(2,852)
Expenses not deductible in determining taxable profit	808	71
Fixed asset temporary timing differences not recognised	6	272
Current year research and development tax credit	(783)	(1,008)
Movement in unrecognised deferred tax asset	1,398	796
Other temporary timing differences not recognised	126	502
Adjustments in respect of prior periods	5	285
<b>Tax for the year</b>	<b>(2,023)</b>	<b>(1,934)</b>

### Factors affecting current and future taxation

On 1 April 2017, the corporation tax rate fell from 20% to 19%. It is expected to fall to 17% from 1 April 2020.

During 2018, a payment of £2.5 million was received from HMRC in respect of the year ended 31 December 2016 and 31 December 2017 R&D tax credit claims. Costs equating to the remaining credit of £0.35 million are currently being queried by HMRC. An equivalent credit of £0.13 million for the year ended 31 December 2018 has been claimed but provided for in full in the financial statements. This enquiry is expected to be resolved with management confident that the full remaining balance will be received in 2019.

As at 31 December 2018, the Group had tax losses available for carry forward of approximately £32.28 million (2017: £29.96 million). The Group has not recognised deferred tax assets of £5.53 million (2017: £5.20 million) relating to carried forward losses and other temporary differences. These deferred tax assets have not been recognised as the Group's management considers that there is insufficient future taxable income, taxable temporary differences and feasible tax-planning strategies to utilise all of the cumulative losses and therefore it is probable that the deferred tax assets will not be realised in full. If future income differs from current projections, this could significantly impact the tax charge or benefit in future periods.

## Notes to the consolidated financial statements continued

### 13. Earnings per share ("EPS")

Basic EPS is calculated by dividing profit or loss for the year by the weighted average number of ordinary shares in issue during the year. Diluted EPS is computed based on the weighted average number of ordinary shares plus the effect of dilutive potential ordinary shares outstanding during the period based on the number of shares that could have been acquired at fair value (determined as the average annual market share price of the Company's shares) based on the monetary value of the subscription rights attached to outstanding share options and warrants.

Dilutive potential ordinary shares include share options and warrants as described in note 2.

The calculation of the basic and diluted EPS as included in the consolidated statement of comprehensive income is based on the following data:

	Year ended 31 December 2018 £'000	Year ended 31 December 2017 £'000
<b>Earnings</b>		
Loss for the year	(16,833)	(12,883)
<b>Number of shares</b>		
Weighted average number of ordinary shares for the purposes of basic EPS	78,992,387	78,141,096
Effect of dilutive potential ordinary shares:		
– share options	—	—
<b>Weighted average number of ordinary shares for the purposes of diluted EPS</b>	<b>78,992,387</b>	<b>78,141,096</b>

In both years the potential ordinary shares were not treated as dilutive as the Group is loss making, therefore the weighted average number of ordinary shares for the purposes of the basic and diluted loss per share were the same.

### 14. Goodwill

	2018 £'000	2017 £'000
As at 1 January and 31 December	1,722	1,722

The Group tests annually for impairment, or more frequently if there are indications that goodwill might be impaired.

Consistent with the segmental reporting, the business has one cash generating unit to which all goodwill arising on acquisitions has been allocated. The recoverable amount of the cash generating unit is determined by reference to fair value of the cash generating unit less estimated costs of disposal. The fair value of the cash generating unit is determined with reference to a Level 1 input, based on the quoted share price in an active market. As at 31 December 2018, the recoverable amount of the cash generating unit was considered to be significantly in excess of its book value.

## 15. Intangible assets

	Acquired intellectual property £'000	Capitalised software development £'000	Licences £'000	Total £'000
<b>Cost:</b>				
At 31 December 2016	2,118	1,903	—	4,021
Additions at cost	—	271	—	271
Disposals	—	—	—	—
At 31 December 2017	2,118	2,174	—	4,292
Additions at cost	—	25	64	89
Disposals	—	—	—	—
<b>At 31 December 2018</b>	<b>2,118</b>	<b>2,199</b>	<b>64</b>	<b>4,381</b>
<b>Accumulated amortisation:</b>				
At 31 December 2016	565	81	—	646
Charge for the year	282	132	—	414
Disposals	—	—	—	—
At 31 December 2017	847	213	—	1,060
Charge for the year	283	98	—	381
Impairment	988	1,644	—	2,632
Disposals	—	—	—	—
<b>At 31 December 2018</b>	<b>2,118</b>	<b>1,955</b>	<b>—</b>	<b>4,073</b>
<b>Carrying amount:</b>				
At 31 December 2016	1,553	1,822	—	3,375
At 31 December 2017	1,271	1,961	—	3,232
<b>At 31 December 2018</b>	<b>—</b>	<b>244</b>	<b>64</b>	<b>308</b>

During Q3 2018, executive management discussed and agreed to cease discovery activities by the Group resulting in the closure of the Welwyn premises and consequential cease of use of the acquired intellectual property ("IP"). As at 31 December 2018 the carrying value of the IP on the balance sheet, net of amortisation recorded, was £1.0 million prior to impairment and the recoverable amount of the asset (value in use) was considered to be £nil. This has been fully impaired to result in a carrying amount of £nil. The capitalised software has not been fully implemented as originally planned because it no longer aligns with the strategic direction of the Company. A portion of the software will remain in use and be amortised over its remaining useful life, the unused portion was deemed to have a recoverable amount (value in use) of £nil. This has been impaired by £1.6 million resulting in a carrying amount of £nil.

## Notes to the consolidated financial statements continued

### 16. Property, plant and equipment

	Leasehold improvements £'000	Plant and machinery £'000	Computer equipment £'000	Total £'000
<b>Cost:</b>				
At 31 December 2016	2,512	3,718	1,253	7,483
Additions	17	29	4	50
Disposals	(8)	(935)	(136)	(1,079)
At 31 December 2017	2,521	2,812	1,121	6,454
Additions	—	20	166	186
Disposals	(261)	(147)	(47)	(455)
<b>At 31 December 2018</b>	<b>2,260</b>	<b>2,685</b>	<b>1,240</b>	<b>6,185</b>
<b>Accumulated depreciation:</b>				
At 31 December 2016	2,001	2,839	1,090	5,930
Charge for the year	460	506	102	1,068
Disposals	(8)	(935)	(136)	(1,079)
At 31 December 2017	2,453	2,410	1,056	5,919
Charge for the year	35	239	55	329
Disposals	(261)	(147)	(47)	(455)
<b>At 31 December 2018</b>	<b>2,227</b>	<b>2,502</b>	<b>1,064</b>	<b>5,793</b>
<b>Carrying amount:</b>				
At 31 December 2016	511	879	163	1,553
At 31 December 2017	68	402	65	535
<b>At 31 December 2018</b>	<b>33</b>	<b>183</b>	<b>176</b>	<b>392</b>

### 17. Investment in associates and joint ventures

Management has performed an impairment assessment and determined that a full impairment of the carrying amount of the investment in PrEP Biopharm Limited is required. The carrying amount of the investment is not considered to be recoverable due to reduced cash flows and changes to the entity's business model and strategic alignment with the Group therefore the consolidated balance sheet value of £4.7 million will be impaired to £nil as at 31 December 2018. The carrying amount of other investments are considered to be fully recoverable.

#### PrEP Biopharm Limited

The following table summarises the movements in the Company's investment in PrEP Biopharm Limited during the year:

	2018 £'000	2017 £'000
As at 1 January	5,421	7,012
Share of loss after tax recognised in the consolidated statement of comprehensive income	(823)	(1,607)
Share of other comprehensive income of associates and joint ventures	100	16
Impairment	(4,698)	—
<b>As at 31 December</b>	<b>—</b>	<b>5,421</b>



Summarised consolidated financial information in respect of PrEP Biopharm Limited and its 100% owned US-based subsidiary, PrEP Biopharm Inc, is set out below and has been prepared in accordance with IFRS:

	31 December 2018 £'000	31 December 2017 £'000
Current assets	643	1,460
Non-current assets	5,083	5,087
Current liabilities	(126)	(402)
Non-current liabilities	(609)	—
<b>Net assets</b>	<b>4,991</b>	<b>6,145</b>
Interest in the associate	3,125	3,848
Goodwill	1,573	1,573
Impairment	(4,698)	—
<b>Carrying amount of the Group's interest in the associate</b>	<b>—</b>	<b>5,421</b>

PrEP Biopharm Limited and its US subsidiary generated no revenue during the period as the activity was that of clinical research.

The total comprehensive loss of £1.3 million (2017: £3.4 million) for the year ended 31 December 2018 included £0.8 million of research and development expenditure (2017: £2.6 million), £0.7 million of administrative expenditure (2017: £1.0 million), and other comprehensive loss of £0.01 million (2017: income of £0.04 million), partially offset by income in respect of a research and development tax credit refund claim.

At 31 December 2018, the Group had cash and cash equivalents of £0.4 million (2017: £0.4 million) and current financial liabilities of £0.09 million (2017: £0.08 million).

The primary place of business of PrEP Biopharm Limited is Queen Mary BioEnterprises Innovation Centre, 42 New Road, London E1 2AX.

### Imutex Limited

The following table summarises the movements in the Company's investment in Imutex Limited during the year:

	2018 £'000	2017 £'000
As at 1 January	7,132	7,138
Additions	—	—
Share of profit/(loss) after tax recognised in the consolidated statement of comprehensive income	84	(6)
<b>As at 31 December</b>	<b>7,216</b>	<b>7,132</b>

Summarised consolidated financial information in respect of Imutex Limited is set out below and has been prepared in accordance with IFRS:

	31 December 2018 £'000	31 December 2017 £'000
Current assets	940	357
Non-current assets	14,247	14,247
Current liabilities	(783)	(371)
<b>Net assets</b>	<b>14,404</b>	<b>14,233</b>
Interest in the joint venture	7,058	6,974
Goodwill	158	158
<b>Carrying amount of the Group's interest in the joint venture</b>	<b>7,216</b>	<b>7,132</b>

Imutex Limited generated no revenue during the period as the activity was that of clinical research. Imutex Limited is a strategic investment which utilises the Group's services to develop vaccine assets.

## Notes to the consolidated financial statements continued

### 17. Investment in associates and joint ventures continued

The total comprehensive profit of £0.2 million (2017: loss of £0.006 million) for the year ended 31 December 2018 included £1.8 million of research and development expenditure (2017: £1.3 million), £0.06 million of administrative expenditure (2017: £0.002 million) and £0.003 million of finance costs (2017: £0.003), partially offset by income in respect of a research and development tax credit refund claim.

At 31 December 2018, Imutex had cash and cash equivalents of £0.07 million (2017: £0.001 million) and current financial liabilities of £0.7 million (2017: £0.4 million). hVIVO plc and PepTcell Limited have a commitment to provide financial support to Imutex Limited in the form of a loan facility which can be drawn down upon (note 27).

The primary place of business of Imutex Limited is The Walbrook Building, 25 Walbrook, London EC4N 8AF.

### 18. Inventories

	31 December 2018 £'000	31 December 2017 £'000
Laboratory and clinical consumables	40	70
Virus – work in progress	633	—
Virus – finished goods	214	1,672
	<b>887</b>	<b>1,742</b>

Inventories expensed in the consolidated statement of comprehensive income are shown within cost of sales or research and development expense. All inventories are carried at the lower of cost or net realisable value in the consolidated statement of financial position.

During 2018, a provision of £1.2 million was recognised against the carrying value of “virus-finished goods” due to a revised forecast of the future commercial usage of one strain of flu virus and cost per vial to the Group. The Group is in the process of manufacturing a new virus strain to use in client studies, costs associated with this development have been capitalised as “virus – work in progress”.

### 19. Trade and other receivables and contract assets

	31 December 2018 £'000	31 December 2017 £'000
Trade receivables	677	981
VAT recoverable	212	—
Other receivables	387	428
Prepayments	506	362
Contract assets	57	417
	<b>1,839</b>	<b>2,188</b>

Contractual payment terms with the Group's clients are typically 30 to 45 days.

The Group recognises expected credit loss provision against trade receivables based on estimated irrecoverable amounts determined by reference to past default experience of the counterparty and an analysis of the counterparty's current financial position. No allowance was recorded in either period presented.

As at 31 December 2018, trade and other receivables of £nil (2017: £975,000) were past due but not impaired. The age profile of these balances is as follows:

	31 December 2018 £'000	31 December 2017 £'000
Up to three months	—	—
Three to six months	—	975
	—	975

The Directors believe that the carrying value of trade and other receivables represents its fair value. In determining the recoverability of trade receivables, the Group considers any change in the credit quality of the receivable from the date credit was granted up to the reporting date.

For details of the Group's credit risk management policies, refer to note 23.

The Group does not hold any collateral as security for its trade and other receivables.

## 20. Cash and cash equivalents

	31 December 2018 £'000	31 December 2017 £'000
Cash at bank and in hand	13,368	20,289

All the Group's cash and cash equivalents at 31 December 2018 and 31 December 2017 are at floating interest rates.

Included in the cash and cash equivalents of the Group at 31 December 2018 was the equivalent of £314,000 (31 December 2017: £2,683,000) denominated in US Dollars and £13,000 denominated in Euros (31 December 2017: £1,000). The remaining cash and cash equivalents balance was denominated in Pounds Sterling (£).

The Directors consider that the carrying value of cash and cash equivalents approximates fair value. For details on the Group's credit risk management, refer to note 23.

## 21. Trade and other payables and contract liabilities

	31 December 2018 £'000	31 December 2017 £'000
Trade payables	1,106	1,103
Other taxes and social security	309	296
VAT payable	—	7
Other payables	81	446
Accruals	1,660	1,513
Contract liabilities	6,546	5,846
	9,702	9,211

Trade payables principally comprise amounts outstanding for trade purchases and ongoing costs. Trade payables are non-interest bearing and are typically settled on 30 to 45-day terms.

The Directors consider that the carrying value of trade and other payables approximates fair value. Included within trade payables of the Group as at 31 December 2018 was the equivalent of £10,000 (31 December 2017: £94,000) denominated in US Dollars and £19,000 (31 December 2017: £nil) denominated in Euros. The remaining trade and other payables are denominated in Pounds Sterling.

The Group has financial risk management policies in place to ensure that trade payables are settled within the credit timeframe and no interest has been charged by any suppliers as a result of late payment of invoices during the reporting periods presented herein (see note 23).

# Notes to the consolidated financial statements continued

## 22. Provisions

	Onerous lease provision £'000	Dilapidations provision £'000	Total £'000
As at 1 January 2018	1,933	347	2,280
Adjustment of provision in the year	13	—	13
Used during the year	(1,136)	—	(1,136)
Unwinding of discount	41	—	41
<b>As at 31 December 2018</b>	<b>851</b>	<b>347</b>	<b>1,198</b>
Current	851	327	1,178
Non-current	—	20	20

An onerous lease provision of £0.9 million (31 December 2017: £1.9 million) represents management's best estimate of the costs to be incurred for the exit of premises leased by the Group after considering the likely outcomes. There is reasonable uncertainty around the likelihood and timing of the exit of leases as negotiations will involve third parties. The adjustment of the provision was recognised due to the vacation of the Manchester site during 2018. The provision is expected to be used during 2019.

Buildings dilapidations of £347,000 (31 December 2017: £347,000) represent the present value of costs to be incurred for the restoration of premises occupied by the Group. £327,000 is expected to be used during 2019 and the remaining £20,000 during 2022.

## 23. Financial risk management

The Group is exposed to the risks that arise from its use of financial instruments. This note describes the objectives, policies and processes of the Group for managing those risks and the methods used to measure them. Risk management is carried out by management under the supervision of the Board of Directors. Management identifies and evaluates financial risks in close co-operation with the business' department heads.

### Capital management

The Group manages its capital to ensure that it will be able to continue as a going concern while maximising the return to stakeholders. The Group is funded principally by equity although long-term and short-term loans have been utilised from time to time.

Financing decisions are made by the Board of Directors based on forecasts of the expected timing and level of capital and operating expenditure required to meet the Group's commitments and development plans.

### Financial assets

At the reporting date, the Group held the following financial assets, all of which were classified as financial assets at amortised cost:

	31 December 2018 £'000	31 December 2017 £'000
Cash and cash equivalents	13,368	20,289
Trade receivables	677	981
Other receivables	387	428
Contract assets	57	417
	<b>14,489</b>	<b>22,115</b>

### Financial liabilities

At the reporting dates, the Group held the following financial liabilities, all of which were classified as other financial liabilities at amortised cost:

	31 December 2018 £'000	31 December 2017 £'000
Trade payables	1,106	1,103
Accruals	1,660	1,513
Repayable lease incentive from related parties	—	400
Other payables	81	46
	<b>2,847</b>	<b>3,062</b>

### Market risk

The Group's activities expose it primarily to the financial risks of changes in foreign currency exchange rates and interest rates. In the year ended 31 December 2018, both these risks are considered to have been minimal.

### Credit risk

Credit risk arises principally from the Group's short-term deposits, cash and cash equivalents and trade and other receivables.

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

The nature of the Group's business and the current stage of its development are such that individual customers can comprise a significant proportion of the Group's trade and other receivables at any point in time. The Group mitigates the associated risk by ensuring that its contracting terms provide for invoicing milestones in advance of the work being carried out and through the close monitoring of the debtor ledger. In addition, many of the Group's clients are either large, global, publicly listed companies or are owned by such entities.

There were no other significant concentrations of credit risk at the reporting date. At 31 December 2018, the Group's trade receivables balance was £677,000 (31 December 2017: £981,000).

For contract assets and trade and other receivables, the Group has applied the IFRS 9 simplified approach and has calculated expected credit losses based on lifetime expected credit losses. The Group has established a provision matrix that is based on the Group's historical credit loss experience, adjusted for forward-looking factors specific to the debtors and the economic environment.

The Group considers a financial asset in default when contractual payment are 90 days past due. However, in certain cases, the Group may also consider a financial asset to be in default when internal or external information indicates that the Group is unlikely to receive the outstanding contractual amounts in full before taking into account any credit enhancements held by the Group. The loss allowance as at 31 December 2018 was determined to be £nil (2017: £nil) and none of the financial assets were past due. Management considers the above measures to be sufficient to control the credit risk exposure.

No collateral is held by the Group as security in relation to its financial assets.

### Liquidity risk management

Liquidity risk is the risk that the Group will encounter difficulty in meeting its financial obligations as they fall due. Ultimate responsibility for liquidity risk management rests with the Board of Directors. The Board of Directors manages liquidity risk by regularly reviewing the Group's cash requirements by reference to short-term cash flow forecasts and medium-term working capital projections.

At 31 December 2018, the Group had cash and cash equivalents of £13.4 million (31 December 2017: £20.3 million).

# Notes to the consolidated financial statements continued

## 23. Financial risk management continued

### Foreign currency risk management

Historically, the Group's exposure to foreign currency risk has been limited, as the majority of its invoicing and payments are in Pounds Sterling. US Dollar expenditure with US suppliers and employee headcount of hVIVO Inc resulted in a Group net cash outflow of \$2.4 million (2017: inflow of \$1.8 million). Foreign exchange risk is managed through the purchase and sale of US Dollars throughout the year.

### Maturity of financial assets and liabilities

All of the Group's non-derivative financial liabilities and its financial assets at 31 December 2018 are either payable or receivable within one year.

## 24. Share capital

	Number	£'000
Issued and fully paid:		
As at 1 January 2017	78,101,077	3,906
Issued pursuant to purchase by Non-Executive Directors – 4 January 2017	12,598	—
Issued pursuant to purchase by Non-Executive Directors – 4 April 2017	15,633	1
Issued pursuant to purchase by Non-Executive Directors – 7 July 2017	21,363	1
Issued pursuant to purchase by Non-Executive Directors – 4 October 2017	23,196	1
As at 31 December 2017	78,173,867	3,909
Issued pursuant to purchase by Non-Executive Directors – 8 January 2018	23,675	1
Issued pursuant to purchase by Non-Executive Directors – 4 April 2018	18,595	1
Issued pursuant to purchase by Non-Executive Directors – 5 July 2018	7,477	—
Employee Share Option Exercise – 9 August 2018	779,600	39
Employee Share Option Exercise – 21 August 2018	205,540	10
Employee Share Option Exercise – 17 September 2018	1,366,320	69
Issued pursuant to purchase by Non-Executive Directors – 4 October 2018	6,420	—
Employee Share Option Exercise – 19 November 2018	12,098	1
<b>As at 31 December 2018</b>	<b>80,593,592</b>	<b>4,030</b>

- Nominal value of share – 5 pence per share
- The rights are as follows:
  - each ordinary share is entitled to one vote at any General Meeting of the Company;
  - the ordinary shares are entitled to participate pro-rata in any distribution of the Company as if they constituted one and the same class;
  - the holders of the ordinary shares are entitled to participate with equal ranking upon a return of capital; and
  - the ordinary shares are not to be redeemed and are not liable to be redeemed at the option of either the Company or the shareholder.

During 2019 to date, 29,887 ordinary shares were allotted pursuant to the quarterly purchase of shares by James Winschel (Non-Executive Director) under the terms of his letters of appointment in part settlement of his Director's fees.

## Options

Share options outstanding at 31 December 2018 have the following expiry date and exercise prices:

Grant date	Number ('000)	Option price (pence)	Date from which exercisable	Expiry date
23 December 2011	215	8.2	3 May 2012	22 December 2021
23 December 2011	215	8.2	23 December 2013	22 December 2021
23 December 2011	215	8.2	23 December 2014	22 December 2021
3 March 2014 – Activiomics	26	101.6	3 March 2014	18 December 2022
21 April 2015	279	337.3	21 April 2018	20 April 2025
17 May 2017 – deferred bonus	119	5.0	17 May 2019	16 May 2027
20 December 2017	1,812	5.0	20 December 2020	19 December 2027
15 January 2018	16	5.0	15 January 2021	14 January 2028
30 July 2018	475	5.0	30 July 2021	29 July 2028
10 August 2018	100	5.0	31 December 2018	9 August 2028
<b>3,472</b>				

Details of share options are disclosed in note 25 to the financial statements.

## Components of equity

The components of equity are as follows:

- share capital and the share premium account, both of which arise on the issue of shares;
- share-based payment reserve, which results from the Company's grant of equity-settled share options to selected employees and Directors;
- merger reserve, which was created as a result of the acquisition by the Company of the entire issued share capital of hVIVO Services Limited in 2012. This reserve is not considered to be distributable;
- other reserve, which relates to unexercised share options issued in respect of the acquisition of Activiomics Limited in 2014; and
- retained deficit, which reflects losses incurred to date.

# Notes to the consolidated financial statements continued

## 25. Share-based payments

### hVIVO plc share option plans

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

On 10 May 2017, the Board adopted the hVIVO plc Long Term Incentive Plan 2017 as a new share scheme available to the Executive Directors and key employees, enabling the grant of options over ordinary shares of 5.0 pence each in the Company. In 2018 the following new grants were made:

- on 15 January 2018, hVIVO granted a further 136,364 options with a fair value of 50 pence per option, over ordinary shares of 5.0 pence each in the Company to employees with an exercise price of £0.05 per share. The options will normally vest on the third anniversary of date of grant, subject to continued employment but no other performance condition. The exercise price payable per share is the nominal price of a share (currently 5.0 pence);
- on 30 July 2018, hVIVO granted a further 474,529 options with a fair value of 64 pence per option, over ordinary shares of 5.0 pence each in the Company to Directors and employees with an exercise price of £0.05 per share. The options will normally vest on the third anniversary of date of grant, subject to continued employment but no other performance condition. The exercise price payable per share is the nominal price of a share (currently 5.0 pence); and
- on 10 August 2018, hVIVO granted a further 100,000 options with a fair value of 63 pence per option, over ordinary shares of 5.0 pence each in the Company to Directors with an exercise price of £0.05 per share. The options will normally vest on the third anniversary of date of grant, subject to continued employment but no other performance conditions. The exercise price payable per share is the nominal price of a share (currently 5.0 pence).

The options are settled in equity once exercised. If the options remain unexercised for a period after ten years from the date of grant, the options expire. Options are forfeited if the employee leaves the Group before the options vest.

Details of the number of share options and the weighted average exercise price ("WAEP") outstanding during the period are as follows:

	31 December 2018		31 December 2017	
	Number (‘000)	WAEP £	Number (‘000)	WAEP £
<b>Outstanding at the beginning of the year</b>	<b>5,812</b>	<b>0.32</b>	3,521	0.54
Forfeited during the year	(687)	0.85	(55)	1.79
Exercised during the year	(2,364)	0.07	—	—
Granted during the year	711	0.05	2,346	0.05
<b>Outstanding at the end of the year</b>	<b>3,472</b>	<b>0.33</b>	5,812	0.32
<b>Exercisable at year end</b>	<b>972</b>	<b>0.97</b>	5,227	0.26

The options outstanding at 31 December 2018 had a weighted average exercise price of £0.33 and a weighted average remaining contractual life of 7.6 years.

The weighted average share price at the date of exercise of the share options exercised during the year ended 31 December 2018 was £0.59.

No expense is recognised for awards that do not ultimately vest because service conditions have not been met. The Company's service conditions consist of continuous employment and satisfaction of individual performance conditions.

The fair values of options granted were calculated using the Black Scholes pricing model. The Group used historical data to estimate expected period to exercise, within the valuation model. Expected volatilities of options outstanding granted prior to the Company's admission to AIM were based on implied volatilities of a sample of listed companies based in similar sectors. The risk-free rate for the expected period to exercise of the option was based on the UK gilt yield curve at the time of the grant.

The Group recognised a charge of £454,000 (31 December 2017: £144,000) related to equity-settled share-based payment transactions during the year.



The assumptions used in the valuation of the options at the grant date are as follows:

	<b>31 December 2018</b>
Expected option life (years)	<b>6.45</b>
Risk free interest rate	<b>1.09% to 1.45%</b>
Expected volatility	<b>35.6% to 90.5%</b>
Expected dividend yield	<b>0.0%</b>

## 26. Pensions

The Group operates a defined contribution pension scheme whose assets are held separately from those of the Group in an independently administered fund. The pension charge represents contributions payable by the Group and amounted to £394,000 for the year (31 December 2017: £462,000). Contributions totalling £82,000 were payable to the fund at the year end and are included within trade and other payables (31 December 2017: £36,000).

## 27. Related party transactions

### Remuneration of key personnel

The remuneration of the Directors, who are the key management personnel of the Group, is shown below:

	<b>Year ended 31 December 2018 £'000</b>	Year ended 31 December 2017 £'000
<b>Executive Directors – aggregate</b>		
Short-term employee benefits and fees	<b>646</b>	591
Compensation from loss of office	<b>265</b>	—
Employer's National Insurance contributions	<b>103</b>	79
Post-employment benefits	<b>17</b>	23
Share-based compensation charge	<b>190</b>	45
	<b>1,221</b>	738
<b>Non-Executive Directors – aggregate</b>		
Short-term employee benefits and fees	<b>103</b>	242
<b>Total Directors' remuneration</b>	<b>1,324</b>	980

Remuneration and benefits paid to the highest paid Director totalled £366,000 (31 December 2017: £301,000).

As indicated in note 24, ordinary shares are allotted pursuant to the quarterly purchase of shares by Jaime Ellertson and James Winschel under the terms of their letters of appointment. These shares are issued at fair market value.

### Amounts outstanding to key personnel

As at 31 December 2018, £nil was due in relation to employer pension contributions (31 December 2017: £2,000).

### Transactions with the Group related parties

#### PrEP Biopharm Limited

During 2018, hVIVO Services Limited provided accounting services to PrEP Biopharm Limited to the value of £0.02 million.

As at 31 December 2018, all amounts invoiced and due from PrEP Biopharm Limited to hVIVO were fully paid.

#### Imutex Limited

On 21 April 2016, PepTcell Limited contracted with hVIVO Services Limited for a Phase IIb FLU-v clinical study to the value of £5.5 million. During the year, £nil (2017: £3.6 million) was recognised as revenue in relation to this clinical study.

During 2018, hVIVO Services provided accounting and regulatory services to Imutex Limited. These services were provided free of charge but amounted to £0.01 million.

As at 31 December 2018, all amounts invoiced and due from PepTcell Limited and Imutex Limited to hVIVO were fully paid.

hVIVO plc has provided a loan of £24,500 to Imutex Limited. Interest on the loan is charged at 5% above the base rate of the Bank of England per annum, the loan is unsecured and is repayable on demand.

## Notes to the consolidated financial statements continued

### 28. Operating lease arrangements

At the reporting date, the Group had outstanding commitments for future minimum lease payments under non-cancellable operating leases, which fall due as follows:

	31 December 2018 £'000	31 December 2017 £'000
Within one year	1,078	1,354
In the second to fifth years inclusive	186	1,323
After five years	—	131
	<b>1,264</b>	<b>2,808</b>

The operating lease commitments include £0.8 million (2017: £1.8 million) in respect of one lease (2017: two leases) which has been identified as being onerous at year end and accordingly, a provision has been made (see note 22).

### 29. Capital commitments

At the reporting date, the Group had capital commitments of £67,000 (31 December 2017: £nil) relating to IT network infrastructure improvements.

### 30. Note to the consolidated statement of cash flows

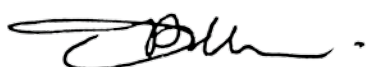
	Year ended 31 December 2018 £'000	Year ended 31 December 2017 £'000
<b>Cash flow from operating activities</b>		
Loss before income tax	(18,856)	(14,817)
Adjustments for:		
Share of loss of associates and joint ventures	738	1,613
Depreciation of property, plant and equipment	329	1,068
Amortisation and impairment of intangible assets	3,013	414
Impairment of investment in associate	4,698	—
Payment of Non-Executive Director fees by issue of shares	31	77
Share-based payment expense	454	144
Finance costs	51	54
Finance income	(58)	(71)
Research and Development Expenditure Credit included in other income	(318)	(90)
Decrease in provisions	(1,082)	(851)
Changes in working capital:		
(Increase)/decrease in inventories	(368)	244
Provision against inventories	1,223	—
Decrease in trade and other receivables and contract assets	349	1,507
Increase in trade and other payables and contract liabilities	503	1,711
<b>Cash used in operations</b>	<b>(9,293)</b>	<b>(8,997)</b>
Finance costs	(51)	(54)
Income tax refund	2,481	4,000
Foreign tax paid	(18)	(14)
<b>Net cash used in operating activities</b>	<b>(6,881)</b>	<b>(5,065)</b>

# Company statement of financial position

at 31 December 2018

	Note	2018 £'000	Restated 2017 £'000
<b>Assets</b>			
<b>Non-current assets</b>			
Investments in subsidiaries	3	21,020	21,020
Investments in associates and joint ventures	4	7,138	21,543
		<b>28,158</b>	42,563
<b>Current assets</b>			
Investments in subsidiaries	3	25,617	32,258
Trade and other receivables	5	49	45
Cash and cash equivalents	6	7,382	11,746
		<b>33,048</b>	44,049
<b>Total assets</b>		<b>61,206</b>	86,612
<b>Equity and liabilities</b>			
<b>Equity</b>			
Share capital	9	4,030	3,909
Share premium account		93,434	93,290
Share-based payment reserve		779	382
Merger reserve		16,530	16,530
Other reserve		211	211
Retained deficit		(54,057)	(27,890)
<b>Total equity</b>		<b>60,927</b>	86,432
<b>Current liabilities</b>			
Trade and other payables	7	279	180
<b>Total liabilities</b>		<b>279</b>	180
<b>Total equity and liabilities</b>		<b>61,206</b>	86,612

The financial statements of hVIVO plc (registered company number 08008725) on pages 77 to 83 were approved and authorised for issue by the Board on 11 April 2019 and signed on its behalf by:



## Dr Trevor Phillips

Executive Chairman

The Company has taken the exemption under section 408 of the Companies Act 2006 not to present the parent company's income statement. The parent company's result for the period ended 31 December 2018 was a loss of £26.2 million (2017: £26.9 million).

The audit fee for the Company is set out in note 7 to the consolidated financial statements.

# Company statement of changes in equity

for the year ended 31 December 2018

	Share capital £'000	Share premium account £'000	Share-based payment reserve £'000	Merger reserve £'000	Other reserve £'000	Retained deficit £'000	Total equity £'000
As at 31 December 2016	3,905	93,217	238	16,530	211	(1,023)	113,078
Proceeds from shares issued:							
Issue of new shares	4	73	—	—	—	—	77
Total transactions with owners in their capacity as owners	4	73	—	—	—	—	77
Loss for the year	—	—	—	—	—	(26,867)	(26,867)
Share-based payment	—	—	144	—	—	—	144
As at 31 December 2017	3,909	93,290	382	16,530	211	(27,890)	86,432
Proceeds from shares issued:							
Issue of new shares	3	28	—	—	—	—	31
Exercise of warrants and share options	118	116	(57)	—	—	—	177
Total transactions with owners in their capacity as owners	121	144	(57)	—	—	—	208
Loss for the year	—	—	—	—	—	(26,167)	(26,167)
Share-based payment	—	—	454	—	—	—	454
<b>As at 31 December 2018</b>	<b>4,030</b>	<b>93,434</b>	<b>779</b>	<b>16,530</b>	<b>211</b>	<b>(54,057)</b>	<b>60,927</b>

# Company statement of cash flows

for the year ended 31 December 2018

	2018 £'000	Restated 2017 £'000
<b>Cash flow from operating activities</b>		
Loss before income tax	(26,167)	(26,867)
Adjustments for:		
Payment of Non-Executive Director fees by issue of shares	31	77
Finance income	(47)	(63)
Impairment of investment in associate	14,405	—
Changes in working capital:		
Increase in trade and other receivables	(4)	(23)
Impairment provision for trade receivables	10,874	26,111
Increase/(decrease) in trade and other payables	99	(117)
<b>Net cash used in operating activities</b>	<b>(809)</b>	<b>(882)</b>
<b>Investing activities</b>		
Capital contribution to subsidiary	—	(1,000)
Movement in loan to subsidiary	(3,779)	(9,864)
Interest received	47	63
<b>Net cash used in investing activities</b>	<b>(3,732)</b>	<b>(10,801)</b>
<b>Financing activities</b>		
Net proceeds from issue of shares	177	—
<b>Net cash generated from financing activities</b>	<b>177</b>	<b>—</b>
<b>Net decrease in cash and cash equivalents</b>	<b>(4,364)</b>	<b>(11,683)</b>
Cash and cash equivalents at the start of year	11,746	23,429
<b>Cash and cash equivalents at the end of year</b>	<b>7,382</b>	<b>11,746</b>

# Notes to the Company financial statements continued

## 1. Principal accounting policies

The separate financial statements of the Company are presented as required by the Companies Act 2006. As permitted by the Act, the separate financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRS") adopted by the European Union.

The financial statements have been prepared on the historical cost basis. The principal accounting policies adopted are the same as those set out in note 2 to the consolidated financial statements, except where noted below.

### Investments

Investments are initially recorded at cost including directly attributable acquisition costs. Investments are reviewed for impairment if events or changes in circumstances indicate that the carrying value may not be recoverable.

### Share-based payments

Refer to note 2 to the consolidated financial statements for the principal accounting policy relating to share-based payments.

Any share-based payment expense arising in relation to employee share options is recharged to the Company's trading subsidiary, hVIVO Services Limited.

## 2. Critical accounting estimates and judgements

### Impairment of investment in subsidiaries

Management considers that the decline in hVIVO plc's share price represents an indicator that the carrying amount of its investment in hVIVO Services Limited may be impaired. Management has completed an impairment assessment to determine whether any impairment loss should be recognised. Critical judgements applied in performing this assessment relate to assumptions around:

- revenues from the continued performance of clinical research services for customers;
- future income streams from leveraging hVIVO's disease in motion database, drug target identification services and asthma precision development services;
- future income streams from the monetisation of hVIVO's intellectual property, including clinical trial tool kits and diagnostics; and
- additional income streams from expanding the above capability into other respiratory disease indications.

Further detail on the assumptions and estimates applied in performing the impairment assessment have been disclosed in note 3. Based on the assessment performed, an additional impairment loss of £10.9 million has been recognised. However, management acknowledges that should any of the future events and cash flows upon which management has based its assumptions not occur, then a greater impairment of the parent company's investment in hVIVO Services Limited would be necessary.

## 3. Investment in subsidiaries

	31 December 2018 £'000	Restated 31 December 2017 £'000
Balance at beginning of year	53,278	68,381
Capital contribution to subsidiary	—	1,000
Movement in loan to Group company	3,779	9,864
Impairment of loan to Group company	(10,874)	(26,111)
Share-based compensation contribution	454	144
Balance at end of year	46,637	53,278
Disclosed as		
Current assets	25,617	32,258
Non-current assets	21,020	21,020

Amounts have been restated for the year ended 31 December 2018, as a result of presenting amounts due from Group undertakings as part of the investment in subsidiaries as a result of the initial application of IFRS 9.

Details of the Company's subsidiaries at 31 December 2018 are as follows:

	Country of incorporation	Holding	Proportion of voting rights and shares held	Nature of business
hVIVO Services Limited	UK	Ordinary shares	100%	Medical and scientific research services
hVIVO Inc	USA	Ordinary shares	100%	Sales and marketing services
Activiomics Limited	UK	Ordinary shares	100%	Dormant

Management has noted an indicator that the carrying amount of the investments of the parent company in its subsidiary, hVIVO Services Limited, may be impaired and have recorded an impairment of £10.9 million against amounts receivable from Group undertakings. The recoverable amount of the investments has been determined to be the value in use of the cash flows generated from the continuing operations of the entity. In performing this assessment, management has applied the following assumptions and estimates:

- cash flows have been projected over a period of ten years from 31 December 2018, which management considers appropriate due to the long-term nature of its clinical research services business and related returns;
- cash inflow projections reflect the following key assumptions:
  - revenues from the continued performance of clinical development services for customers;
  - revenues in the short to medium term are based on contracted amounts, contracts currently in negotiation and estimates of clinical development services to be performed in hVIVO's key areas of respiratory disease focus. hVIVO's key areas of respiratory disease focus are currently flu, RSV and asthma, with the expectation that services will expand into other respiratory disease indications including COPD;
  - for financial modelling purposes, it has been assumed that total revenue increases from 2018 and for the five years to 2022, with total revenue for 2022 of approximately £34 million per annum, which is then assumed to remain constant in real terms for the remainder of the projected period;
- cash outflows, which include contract delivery costs, operating expenses, research spend and capital spend are assumed to be consistent with current experience;
- cash flows beyond the ten-year period were extrapolated using a terminal growth rate of 2%, which is management's estimate of the long-term average growth rate for the UK market, the principal geography in which the entity operates; and
- a pre-tax discount rate of 12.34% has been applied in discounting cash flows to their present value, which has been benchmarked against available sources for comparable companies.

Cash flow projections are most sensitive to the assumptions regarding:

- revenue and margins from clinical development services, including:
  - number of customer studies and contract values;
  - number and price of volunteers per study;
  - mix of studies across disease indications;
  - expansion of the clinical development services market for each disease indication;
  - building and conversion of hVIVO's sales funnel across disease indications, including consideration of changing market share and threat from competition; and
- changes in the discount rate.

At 31 December 2018, there is limited headroom in respect of the carrying value of the parent company's investment in hVIVO Services Limited. Should any of the future events and cash flow assumptions upon which management has based its value in use calculation not occur or change adversely, a greater impairment of the investment in hVIVO services Limited would be necessary.

## Notes to the Company financial statements continued

### 4. Investment in associates and joint ventures

Management has performed an impairment assessment and determined that a full impairment of the carrying amount of the investment in PrEP Biopharm Limited is required. The carrying amount of the investment is not considered to be recoverable due to reduced cash flows and changes to the entity's business model therefore the Company balance sheet value of £14.4 million will be impaired to £nil as at 31 December 2018. The carrying amount of other investments are considered to be fully recoverable.

#### PrEP Biopharm Limited

	2018 £'000	2017 £'000
As at 1 January	14,405	14,405
Impairment	(14,405)	—
<b>As at 31 December</b>	<b>—</b>	<b>14,405</b>

#### Imutex Limited

There was no movement in the Company's investment in Imutex Limited during the year:

	2018 £'000	2017 £'000
<b>As at 31 December</b>	<b>7,138</b>	<b>7,138</b>

### 5. Trade and other receivables

	31 December 2018 £'000	31 December 2017 £'000
Other receivables	41	34
Prepayments	8	11
	<b>49</b>	<b>45</b>

### 6. Cash and cash equivalents

	31 December 2018 £'000	31 December 2017 £'000
Cash at bank and in hand	7,382	11,746

All of the Group's cash and cash equivalents at 31 December 2018 are at floating interest rates and are all denominated in Pounds Sterling.

The Directors consider that the carrying value of cash and cash equivalents approximates their fair value. For details on the Company's credit risk management, refer to note 23 to the consolidated financial statements.

### 7. Trade and other payables

	31 December 2018 £'000	31 December 2017 £'000
Trade payables	18	51
Social security and other taxes	28	45
Accruals	233	84
	<b>279</b>	<b>180</b>



## 8. Financial instruments

### Principal financial instruments

The Company's financial instruments that principally expose it to financial risks are as follows:

- trade and other receivables;
- trade and other payables; and
- cash and cash equivalents.

### Financial assets

At the reporting date, the Company held the following financial assets:

	31 December 2018 £'000	Restated 31 December 2017 £'000
Cash and cash equivalents	7,382	11,746
Other receivables	41	34
	<b>7,423</b>	<b>11,780</b>

### Financial liabilities

At the reporting dates, the Company held the following financial liabilities, all of which were classified as other financial liabilities:

	31 December 2018 £'000	31 December 2017 £'000
Trade payables	18	51
Accruals	233	84
	<b>251</b>	<b>135</b>

Refer to note 23 to the consolidated financial statements for more information.

## 9. Share capital

Refer to note 24 to the consolidated financial statements.

## 10. Share-based payments

Refer to note 25 to the consolidated financial statements.

## 11. Related party transactions

### Remuneration of key personnel

The remuneration of the Directors, who are the key management personnel of the Group, is shown in note 27 to the consolidated financial statements.

## Advisers

### **Auditor**

#### **Ernst & Young LLP**

Chartered Accountants  
1 More London Place  
London SE1 2AF

### **Nominated adviser and broker**

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### **Registered in England and Wales**

Registered number 08008725

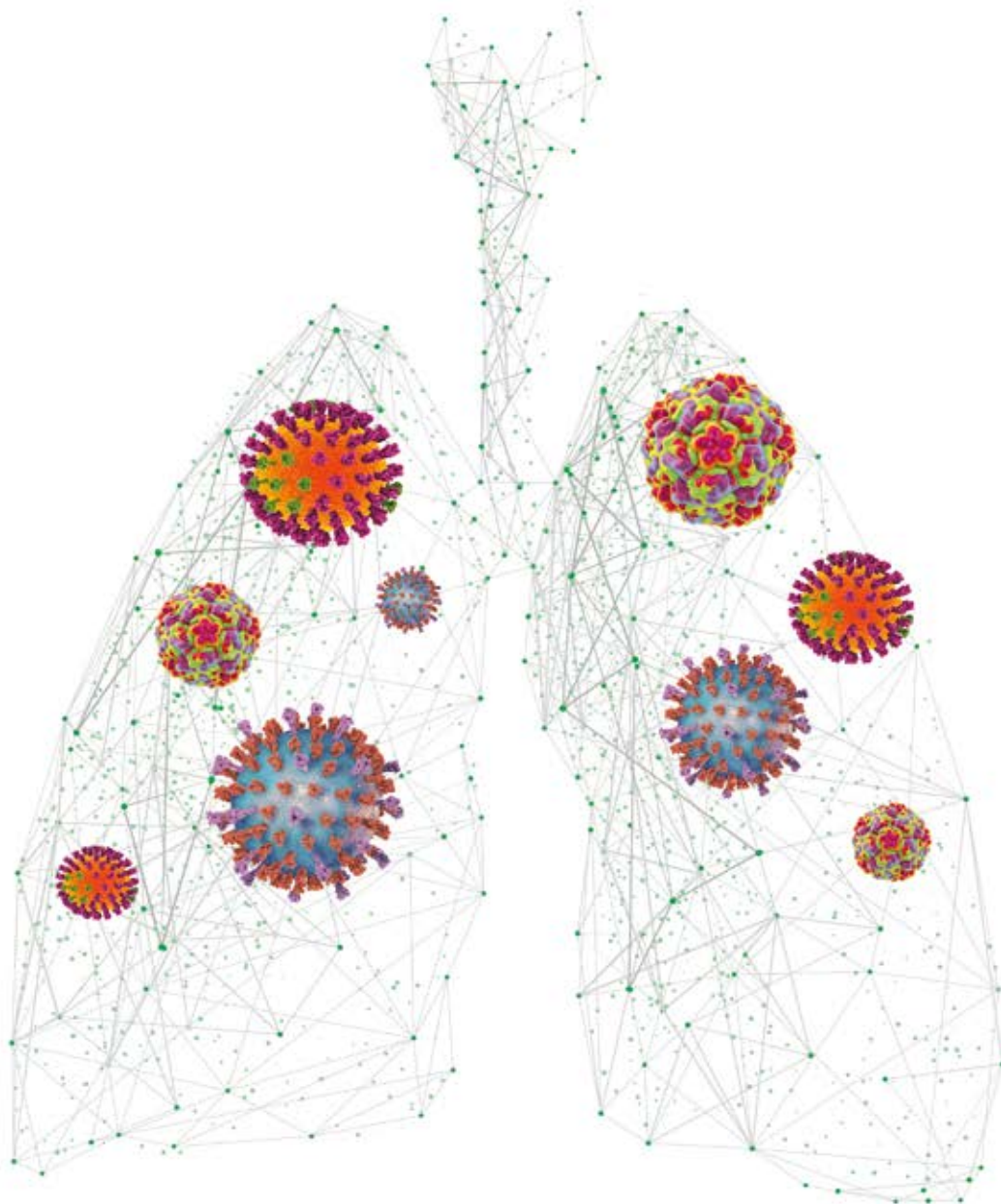
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