



**hVIVO plc**  
("hVIVO" or the "Company")

**Preliminary Results**  
**For the year ended 31 December 2018**  
**Transitional year, revenues increasing, operating costs reducing**

- *Re-focussed services business model with strong pipeline of contract opportunities*
- *Good progress on business turnaround, R&D expense significantly reduced and focussed specifically on opportunities to support the enhancement of our development services*
- *Cost base and expenditure reductions implemented to support future growth and provide a pathway to cash generation*
- *Positive Phase IIb FLU-v results*

**London, UK - 11 April 2019: hVIVO plc (AIM: HVO)**, an industry leading clinical development services business pioneering human disease models based upon viral challenge, today announces its preliminary results for the year ended 31 December 2018.

**Financial Highlights: Service revenue increasing, financial impact of operating efficiencies and cost savings will be fully recognised across 2019 and 2020**

- Revenue & Other Income up 10.5% to £13.6 million (2017: £12.3 million)
- Adjusted Loss Before Tax\* down 27.6% to £9.6 million (2017: £13.2 million)
- Loss Before Tax - £18.9 million (2017: £14.8 million)
- Cash and cash equivalents of £13.4 million (2017: £20.3 million)
- Research and development expense down 21% to £4.8 million (2017: £6.1 million)
- Current cost reduction programmes are forecasted to deliver improvements which will reduce operating expense by a total of £3.9 million, across 2018, 2019 and 2020

\* 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 (3) provision of £1.2 million made against certain virus stock with consolidated balance sheet value of £1.2 million

**Operational Highlights: Good progress on turnaround, enabling greater study throughput and establishing a strong foundation for driving organic growth strategy**

- Increased demand for services translating to a strong base of revenues 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 re-focussed services business model and R&D expense 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

**Dr Trevor Phillips, Executive Chairman, commented:**

*"I am proud of all that the team has achieved in 2018 and in particular the progress made turning around the business following the management changes instigated in April 2018. As a result, we have been able to quickly re-focus the business and make the necessary operational decisions to ensure we are positioned to run an efficient business that can become sustainably profitable in the medium term. This will allow us to maximise the opportunities for our services that will translate into the delivery of shareholder value. We have made progress in addressing business operations, taking multiple steps to decrease the cost base and begin to reduce losses and generate profit. There is still more to do. We expect to see the full benefit of the actions taken in 2018, and now in 2019, during 2020.*

*"In addition to the growth in our core services business, we were pleased to announce positive data for FLU-v, the late stage, broad spectrum universal influenza vaccine candidate in our joint venture Imutex. We continue to make progress regarding strategic discussions related to the assets in this JV, helping to maximise the strategic options available. 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.*

*"The Company is now stronger and better placed than ever to succeed in its core business and to become a sustainably profitable business in the medium term. Based on the contracted work and the potential contract opportunities currently under discussion, I believe 2019 will be a positive and progressive year for hVIVO."*

**Analyst meeting**

A presentation and webcast for analysts will be held at 09.00am BST this morning, 11 April 2019 at the offices of FTI Consulting, 200 Aldersgate, Aldersgate Street, London, EC1A 4HD, with registration and coffee from 08.45am. A webcast recording of the event will be available on the Company's website – <http://hvivo.com/investors/presentations-webcasts/>. For further details, please contact FTI on 020 3727 1000.

**For further information please contact:**

**hVIVO plc**

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**Notes to Editors:**

hVIVO plc ("hVIVO") is pioneering a human-based clinical trial platform to accelerate drug and vaccine development in respiratory and infectious diseases. Leveraging human disease models in flu, RSV, HRV and respiratory indications, the hVIVO platform captures disease in motion, illuminating the entire disease life cycle from healthy to sick and back to health. Based in the UK, market leader hVIVO has conducted more than 50 clinical studies and inoculated over 2500 volunteers.

**Forward-looking statements**

*This announcement includes statements that are, or may be deemed to be, forward-looking statements. These forward-looking statements can be identified by the use of forward-looking*

*terminology, including the terms anticipates, believes, estimates, expects, intends, may, plans, projects, should or will, or, in each case, their negative or other variations or comparable terminology, or by discussions of strategy, plans, objectives, goals, future events or intentions. These forward-looking statements include all matters that are not historical facts. Any forward-looking statements in this announcement reflect the Group's (or, as the case may be, the hVIVO directors') current view with respect to future events and are subject to risks relating to future events and other risks, uncertainties and assumptions relating to the Group's operations, results of operations and growth strategy. Investors should specifically consider the factors identified in this announcement which could cause actual results to differ before making an investment decision.*

## **Executive Chairman's Statement**

### **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 re-focused 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;
- Reduced costs as the model requires a relatively small number of subjects investigated over a shorter period of time

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 re-focussed 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.

#### **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 re-focussed 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 consultant 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, standalone, 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, standalone, influenza vaccine candidate

- Positive results from the Phase IIb field (FLU-v 003) and challenge Studies (FLU-v 004) were announced in 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 II 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 Biopharma 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 re-focussed business model

### **Board changes**

- Kym Denny, Chief Executive Officer, Graham Yeatman, Chief Finance 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 in January 2019.

### **Financial Review**

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 £2.9m 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), 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

trial service offerings 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 cashflows 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, 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 £0.3m (2017 £0.3m) 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**

Management have considered its forecast of the Company's cash requirements reflecting contracted and future revenue and the resulting net cash outflows. 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.

### **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**

**hVIVO plc**

**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.

# hVIVO plc

## Consolidated Statement of Financial Position

As 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>	<b>18,042</b>
<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>	<b>26,844</b>
<b>Total assets</b>		<b>28,233</b>	<b>44,886</b>
<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>	<b>33,395</b>
<b>Non-current liabilities</b>			
Provisions	22	20	2,280
		<b>20</b>	<b>2,280</b>
<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>	<b>9,211</b>
<b>Total liabilities</b>		<b>10,900</b>	<b>11,491</b>
<b>Total liabilities and equity</b>		<b>28,233</b>	<b>44,886</b>

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

## hVIVO plc

### 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
<b>As at 31 December 2016</b>	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)
<b>As at 31 December 2017</b>	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.

## hVIVO plc

### 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.

**hVIVO plc**

## **Notes to the Consolidated Financial Statements**

### **1. Basis of the announcement**

The audited preliminary results for the year ended 31 December 2017 were approved by the Board of Directors on 11 April 2018. The preliminary results do not constitute full accounts within the meaning of section 434 of the Companies Act 2006 but are derived from accounts for the year ended 31 December 2018 and year ended 31 December 2017.

The preliminary announcement is prepared on the same basis as set out in the statutory accounts for the year ended 31 December 2018. Those accounts upon which the auditors issued an unqualified opinion, also had no statement under section 498(2) or (3) of the Companies Act 2006.

While the financial information included in this preliminary announcement has been prepared in accordance with the recognition and measurement criteria of International Financial Reporting Standards (IFRS), as adopted by the European Union (EU), this announcement does not in itself contain sufficient information to comply with IFRS.

The Company is a limited liability company incorporated and domiciled in England & Wales and whose shares are quoted on AIM, a market operated by The London Stock Exchange. For the purpose of the consolidated and individual financial statements, the results and financial position of each Group company are expressed in pounds Sterling (£).

The statutory accounts for the financial year ended 31 December 2018 will be delivered to the Registrar of Companies following the Company's Annual General Meeting.

### **Going concern**

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 & 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 are 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 have 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.

## 2. Other income

Other income includes £2.3 million (2017: £1.3 million) of public health cost-share grant awarded by US DARPA (Defense Advanced Research Projects Agency) 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.

## 3. 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
Tax for the year	<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.

#### **4. Earnings per share ("EPS")**

Basic earnings per share 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
Earnings		
Loss for the year	(16,833)	(12,883)
Number of shares		
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	—	—
Weighted average number of ordinary shares for the purposes of diluted EPS	78,992,387	78,141,096

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.

## 5. 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 research & 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.

## 6. 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	<b>14,247</b>	14,247
Current liabilities	<b>(783)</b>	(371)
<b>Net assets</b>	<b>14,404</b>	14,233
Interest in the joint venture	<b>7,058</b>	6,974
Goodwill	<b>158</b>	158
<b>Carrying amount of the Group's interest in the joint venture</b>	<b>7,216</b>	7,132

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.

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

## 7. Inventories

	<b>31 December</b>	31 December
	<b>2018</b>	2017
	<b>£'000</b>	£'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 £1.2m 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”.

## 8. Trade and other receivables

	<b>31 December</b>	31 December
	<b>2018</b>	2017
	<b>£'000</b>	£'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>

## 9. Cash and cash equivalents

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

## 10. Trade and other payables

	<b>31 December</b>	31 December
	<b>2018</b>	2017
	<b>£'000</b>	£'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
	<b>9,702</b>	<b>9,211</b>

## 11. 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.

## 12. 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>