



For immediate release 07:00: 20 April 2017

HVIVO PLC
("hVIVO" or the "Company")

**AUDITED PRELIMINARY RESULTS
FOR THE YEAR ENDED 31 DECEMBER 2016**

hVIVO plc (AIM: HVO), the pioneer of human disease models, is pleased to announce its audited preliminary results for the year ended 31 December 2016.

Financial Highlights

- Revenue of £19.9 million (2015: £7.7 million), includes £7.3 million from third-party client engagements and £12.5 million from equity investments (£9.7 million from the three PrEP-001 Phase IIa clinical studies and £2.8 million from the FLU-v Phase IIb clinical study)
- Gross profit of £4.2 million and gross profit margin of 21.3% (2015: gross profit £2.5 million and gross profit margin 31.8%), with margin dampened by clinical studies with equity investments
- Research and development (R&D) expense was £6.3 million (2015: £10.2 million) and is lower, as expected, compared to previous years, due to the timing of phases and weighting of costs of our discovery research programmes, with greater R&D expense in previous years from undertaking the sample clinical studies and subsequent third party transcriptomic analysis
- Administrative expenses were £13.8 million (2015: £13.7 million) with costs maintained primarily due to non-capitalisable costs of investment in a medical management technology platform, leveraging technology to improve efficiency, partially offset by ongoing cost savings and other efficiency initiatives
- Short-term deposits, cash and cash equivalents of £25.7 million at 31 December 2016 (2015: £51.2 million), extending cash runway into H2 2018

Operational Highlights

- Filed hVIVO's first patent application in severe flu as a result of our pathomics-informed drug target discovery, and in parallel, progressed the selection of a severe flu compound against this target, positioning hVIVO to lead the way in developing the first treatments for this area of high unmet need
- Advanced a potentially ground-breaking biological algorithm for predicting who will experience asthma worsening before symptoms emerge
- Conducted three Phase IIa clinical studies for PrEP-001 designed to address key clinical development questions, regarding target indications (both flu and cold), dosing regimens (daily dosing), and optimal field study population (healthy adults)

- Contracted our second equity investment in April 2016, acquiring a 49.0% interest in Imutex Limited for £7.0 million, which holds two clinical stage vaccine platforms in universal flu (FLU-v) and mosquito-borne disease (AGS-v)
- Advanced three clinical studies with FLU-v and AGS-v, with initial data read-outs expected in 2017

Commenting on today's results, Kym Denny, Chief Executive Officer, said:

“In 2016 we leveraged the hVIVO platform to advance our equity investment-based clinical assets, while simultaneously converting our growing insight in flu and asthma into new inventions. Securing PrEP-001’s clinical proof-of-concept in flu was a key achievement. Whilst PrEP-001’s asthma trial results were not what we hoped for, our ongoing analysis of the data, in combination with hVIVO’s proprietary common cold datasets, will inform future hypothesis for testing regarding specific asthma subtypes. In the meantime PrEP Biopharm will progress the product’s development in the healthy adult population. Our Imutex investment brought us a universal flu vaccine and a mosquito-borne illness vaccine, both of which we were able to accelerate into the clinic, with initial data read outs expected in 2017.

Further to the platform’s product testing activities, the hVIVO R&D team took the insight generated from previous years’ samples and arrived at a qualified drug target and corresponding candidate compound list for severe flu, as well as produced our first biological algorithm for predicting patients at risk of asthma worsening before symptoms arise.

We look forward to advancing our inventions and clinical stage assets in 2017, as we seek to utilise our revolutionary platform and precision development approach to deliver respiratory precision medicine-based therapies.”

For further information please contact:

hVIVO plc +44 207 756 1300
 Kym Denny (Chief Executive Officer)
 Graham Yeatman (Chief Financial & Business Officer)

Media Enquiries +44 203 021 3933 /
 +44 7854 979 420

Colin Paterson (Director of Marketing, Communication and Public Relations)

Numis Securities Limited +44 207 260 1000
 Michael Meade / Freddie Barnfield (Nominated Adviser)
 James Black / Michael Burke (Corporate Broking)

FTI Consulting
 Simon Conway / Victoria Foster Mitchell (UK) +44 203 727 1000
 John Capodanno / Evan Smith (US) +1 212 850 5705

Notes to Editors:

hVIVO plc (“hVIVO”), a specialty biopharma company with discovery and clinical testing capabilities, is pioneering a human-based analytical platform to accelerate drug discovery and development in respiratory and infectious diseases. Leveraging human disease models in flu, RSV and asthma exacerbation, 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 45 clinical studies, inoculated over 2000 volunteers and has three first-in-class therapies currently in development with a growing pre-clinical pipeline.

CHIEF EXECUTIVE OFFICER'S STATEMENT

In 2016, the insights enabled by our “disease in motion” human disease models allowed us to achieve significant steps in our quest for precision medicines in respiratory and infectious diseases. After three years of collecting and qualifying influenza (flu) disease in motion samples, we were able to demonstrate ‘severe flu’ as having a different pathophysiology to ‘normal flu’, opening up the ability to predict, diagnose and treat severe flu for the very first time. Additionally, from our new asthma exacerbation disease model, we were able to advance a potentially ground-breaking biological algorithm that can predict, up to two days before symptoms emerge, who will experience asthma worsening due to the common cold. Leveraging our platform for its product testing capabilities, we advanced PrEP-001 through three clinical studies aimed at widening its application, selecting the optimal dosing regimen, and investigating the best patient population in which to advance development. Lastly, we formed a joint venture with SEEK Group (SEEK) to develop two clinical stage vaccine assets in universal flu and mosquito-borne diseases, which we advanced into Phase IIb and first-in-man studies, respectively.

Severe flu – first pathomics patent application filed

Over hVIVO’s 25 years of experience researching flu it has become clear that there are significant gaps in existing treatments and vaccines. We believe we can overcome these gaps by better understanding the immune response to flu infection. In particular, hVIVO noted that there were no treatments for severe flu. This translates into a worrying economic reality: in the US alone, there are 200,000 cases of severe flu annually, 20% of which develop acute respiratory distress syndrome (ARDS) and cause \$13.8 billion in hospital costs. These figures can be expected to increase exponentially in pandemic outbreaks.

As such, hVIVO turned the power of our platform on severe flu in order to illuminate the correct drug targets to produce a positive therapeutic effect. Through our pathomics process, we arrived at a qualified pathway component for our severe flu drug target in under 18 months and filed our first patent application around this discovery in early July 2016. The invention in this initial patent application aims to protect our pathomics-informed drug target (HVO-001), with additional patent applications to follow that address novel and inventive use of the associated pathway and disease activity biomarkers.

Based on both *in vitro* and human *ex vivo* disease relevant assays, we are currently in the compound selection stage for our severe flu drug candidate. We believe our pathomics insights and our efforts over the past three years to distinguish those pathways involved in severe flu positions hVIVO to lead the charge in defining and treating this area of high unmet medical need.

Data mining – translating insights to products

Once we had identified a biological distinction between severe and normal flu, we turned to data mining of our time-course, disease in motion samples to reveal patterns and meaningful correlations between clinical, cellular and molecular data. Our goal is subsequently to identify molecular signatures and biological algorithms that can serve as predictor tools and patient stratification guides. For flu, we have identified a candidate invention to distinguish who is contagious well in advance of showing symptoms (patent application filed in February 2017) and we are currently working to identify a molecular signature for predicting who will develop severe flu. Qualification of these discoveries is ongoing in 2017, and we continue to mine our existing discovery data sets with the goal of deriving additional commercially viable inventions.

In addition to flu, 2016 saw hVIVO progress data mining of samples from our newest human model in asthma exacerbation. We identified a time-course signature in our disease in motion data that pointed to an ability to predict who would suffer asthma worsening when infected with the common cold. By the end of 2016, we had completed a third party analysis of that discovery, which we strengthened via correlation analysis and grouping, in addition to predictive modelling. The result was a refined algorithm that can potentially predict up to two days in advance of any symptoms, who will experience a worsening of their asthma (patent application filed in April 2017). We see this invention being further refined as we zero in on asthma subtypes. The discovery holds promise for both precision drug development as well as precision diagnostics. As a development tool, the asthma worsening predictor can help select patients for enrolment into clinical trials; as a diagnostic or digital health tool, it could help patients at risk proactively and appropriately seek or avoid therapeutic interventions, thereby preventing serious exacerbations and morbidity for patients and substantially reducing healthcare costs.

Advancing PrEP-001 – a novel pan-viral prophylactic

Less than 18 months after our investment in PrEP Biopharm Limited (PrEP Biopharm) and its lead product PrEP-001, hVIVO has completed three Phase IIa studies for PrEP-001: a proof-of-concept (POC) in flu, a dose ranging (durability) study, both using healthy volunteers, and a study exploring an additional patient population (asthmatics). These studies were designed to answer early in development crucial questions regarding breadth of viral coverage, dosing regimens and optimal field study patient populations. They provide the ability to sufficiently explore study variables before committing to Phase III – a step that is imperative in diseases such as asthma, where taking a “one-size-fits-all” approach is not viable for bringing more targeted and effective new medicines to market, highlighting how little is known regarding asthma’s subtype populations.

PrEP-001 is a nasally administered, broad-spectrum agent that leverages the innate immune system to prevent upper respiratory tract viral infections. The PrEP-001 Phase IIa flu POC study, which achieved positive results and was announced in June 2016, was a key highlight of the first half of 2016. Severity and duration of flu symptoms were reduced two-fold in healthy volunteers. Following the previous successful results in the common cold POC study in 2014, this study demonstrated PrEP-001’s potential as a pan-viral prophylactic for flu and cold infections that cause more than 500 million infections per annum.

The PrEP-001 Phase IIa durability and asthma exploratory studies were designed to provide valuable insights for PrEP-001 on dosing regimens and future study patient populations, respectively, and build on the profile of the drug following the positive flu and cold POC challenge studies in healthy volunteers. Both of these trials were initiated in 2016 and reported post-period in February 2017. Both studies demonstrated that PrEP-001 was safe and well tolerated, with the adverse event profile being similar in active and placebo arms and consistent with previous studies with the drug.

The durability study was conducted in healthy subjects challenged with human rhinovirus 16 (HRV-16) to explore the impact of two potential dosing schedules for PrEP-001 beyond the once daily dosing already established in prior studies. Together, with the previous study in common cold, the results showed that weekly and twice weekly dosing were not sufficient to sustain a meaningful prophylactic effect and once daily dosing may be the more effective dosing regimen.

The next Phase IIa trial investigated the effect of PrEP-001 in a different patient population, namely people with asthma. The trial involved a non-stratified approach in patients with mild to

moderate controlled asthma, challenging them with HRV-16. The primary endpoint was patient assessed TSS, expressed as an average (Area Under the Curve (AUC)). The trial failed to meet its primary endpoint, with lower than expected symptoms reported in both the placebo and treatment groups, hinting that a broad, controlled asthma patient population responds differently to cold infections than a more homogeneous healthy population.

We subsequently took a deeper look into the data to see if we could detect any trends that would help pinpoint the key differences in the clinical characteristics and biology of the patient population and therefore identify key features of responders and non-responders. We identified that there was a significantly higher number of patients post common cold infection with no symptoms in the active group compared to placebo. This suggests that there was potentially a strong responder subtype. In addition, when exploring individual symptoms (as opposed to an average), we found in a modified intent-to-treat (ITT) analysis that the TSS peak was significantly lower in the active compared to the placebo.

Work is now ongoing to fully characterise the responder subgroup discussed above at the clinical, cellular and molecular level. Whilst PrEP-001's asthma trial results were not what we hoped for, hVIVO is in a privileged position of being in possession of full time-course data for healthy, mild uncontrolled, and controlled mild to moderate asthma patients challenged with the common cold virus and we will be leveraging this dataset to tease out the granular differences (i.e. phenotypes and endotypes) between asthma patients and how they respond to viral infection. In the meantime, PrEP Biopharm will advance the development of PrEP-001 in the healthy adult population, with Phase IIb planned for H1 2018.

Expanding our pipeline – Imutex Limited

In April 2016, hVIVO completed its second equity investment, forming a joint venture in a new company, Imutex Limited (Imutex), with fellow investor PepTcell Limited, also known as the SEEK Group (SEEK). The partnership was formed to develop two clinical stage vaccine platforms in universal flu (FLU-v) and mosquito-borne diseases (AGS-v).

Such vaccines are key public health priorities identified by the Centers for Disease Control and Prevention (CDC), the US National Institute of Health (NIH), and other international health authorities. Since the announcement, hVIVO and SEEK have been collaborating to accelerate development of both vaccines. Both products have the potential to qualify for US Food and Drug Administration (FDA) Fast Track designation, depending on the outcome of the trials being conducted in 2016/2017.

Outlook

In 2016, we made significant strides in leveraging our platform to test new products and harvest our biological insights. We advanced the development of our three clinical stage assets. Separately and concurrently, we pivoted from building our collection of disease in motion samples to mining and converting the biological insights they reveal into precision medicine-based therapies and tools.

To date, our equity investment assets, namely PrEP-001 and FLU-v, have benefited from our platform, primarily as a rapid, sophisticated testing tool. As we now move forward with converting our insight into precision development tools and diagnostics, we will add much deeper value to these products and to future products we collaborate on and test in our platform. To that end, in 2017 we will be focusing on mining our time-course samples across common cold challenged data sets to search for an asthmatic subgroup of PrEP-001 responders, as well

as a phenotype associated with susceptibility to viral infection. In the meantime, PrEP Biopharm will press ahead with a PrEP-001 Phase IIb study in healthy adults.

We also expect the development of the assets from our most recent investment in Imutex to continue at its rapid pace, with data from the two FLU-v Phase IIb studies, and the AGS-v Phase I study, expected later this year. With flu remaining a key priority for many public health authorities, we will look to advance to lead candidate selection and capitalise on the opportunity to fast track development of a potential severe flu drug treatment, as well as further progressing Imutex's FLU-v.

We plan to continue to progress the application of our asthma worsening predictor tool as we deepen our understanding of asthma subtypes, and qualify our severe flu predictor tool. Along with the flu contagiousness patent application filed in February 2017, we expect the development of additional tools for flu and asthma to continue in 2017.

In the second half of 2016, our testing facilities were leveraged to their highest capacity of the year, with the completion of PrEP-001 durability and asthma exploratory studies, the start of the FLU-v study, and the restarting of a client study that was delayed from H1 2016. We successfully managed the workload of the PrEP-001 and FLU-v studies to accommodate the client study, such that the PrEP-001 and client studies completed their quarantines in Q4 2016, with the expanded FLU-v study achieving its last quarantine cohort in March 2017. Demand continues to rebuild for flu, with strong funding opportunities coming particularly from US government agencies. Our flexible operating model allows us dynamically to balance competing demands for our capacity and workload, to meet our own and our clients' development expectations. Our commercial operating model is now such that we seek to balance and flex our platform's capacity and workload between engagements with our equity investments, our strategically important clients and our own discovery work (together with the associated funding streams from client revenue and government grants), such that we achieve the optimum mixture of work type to advance our products and progress adoption of our models depending on priority and best value. We also continue to make significant strides in achieving a more agile, flexible and efficient operating model, together with implementing other cost savings initiatives and leveraging technology in our process, which seek to extend our cash runway and prioritise our investment spend to achieving near term value inflection points and commercialisation opportunities.

As we move into 2017, we stand at the forefront of the development of precision medicine for respiratory and infectious diseases, and model platform, converting biological insights from our disease in motion samples into proprietary inventions that will, over time, help to revolutionise how we treat respiratory and infectious diseases such as asthma and flu. I look forward to updating you further as we achieve key milestones and I would like to thank our staff, patients, customers, partners and investors for their invaluable support in making all of our 2016 achievements possible.



Kym Denny
Chief Executive Officer
19 April 2017

Sources:

- CDC.gov, Influenza Activity – United States, 2013-2014 Season and Composition of the 2014-15 Influenza Vaccine, Accessed 10/15
- Woods et al (2015), *Am J Physiol Lung Cell Mol Physiol* 38(9): L912-L921
- Howard WA et al (2011), *influenzajournal.com*,
- Wisen, J., et al (2012), *Annals of Intensive Care*, 2:41
- Molinari (2007), *Vaccine* 25(27) :5086–5096
- Fendrick et. al. (2003), *Arch Intern Med.* 163(4):487-494

FINANCIAL REVIEW

During 2016, hVIVO completed three PrEP-001 Phase IIa clinical studies, contracted its equity investment in Imutex Limited (April 2016) and made significant progress in conducting the FLU-v Phase IIb clinical study for PepTcell Limited. A third party client study postponed from H1 2016 was restarted and completed in H2 2016, which added to improved utilisation and gross profit margin in the second half of the year. hVIVO continued to invest in its research and development programme to leverage its collection of disease in motion samples to provide biological insights and further develop its clinical assets.

Financial KPIs	2016	2015
Short-term deposits, cash and cash equivalents	£25.7m	£51.2m
Revenue	£19.9m	£7.7m
Gross profit	£4.2m	£2.5m
Gross profit margin	21.3%	31.8%
Research and development expense	£(6.3)m	£(10.2)m
Administrative expense	£(13.8)m	£(13.7)m
Share of loss of associates and joint ventures	£(7.4)m	£(0.1)m
Loss for the year	£(17.9)m	£(17.9)m

Revenue

Revenue for the year ended 31 December 2016 was £19.9 million (2015: £7.7 million). Revenue includes £7.3 million from third party client engagements and £12.5 million from equity investments (£9.7 million from the three PrEP-001 Phase IIa clinical studies and £2.8 million from the PepTcell Limited FLU-v Phase IIb clinical study). The PepTcell Limited FLU-v study is included in revenue following the reversal in accounting treatment of the Imutex Limited transaction, announced on 13 April 2017.

During 2016, the Group delivered final study data for the PrEP Biopharm Limited flu and asthma licence arrangements, leading to recognition of revenue and related costs against the delivery of these two licences on a “completed” basis. Revenue from the PrEP-001 durability study, FLU-v study and other third party client studies was recognised on a percentage of completion basis.

Research and development (“R&D”) expense

R&D expense was £6.3 million (2015: £10.2 million) and is lower, as expected, compared to previous years, due to the timing of phases and weightings of cost of our various discovery research programmes, with greater R&D expense in previous years from undertaking the sample clinical studies and subsequent third party transcriptomic analysis.

Share of loss of associates and joint ventures

Share of loss of associates and joint ventures was £7.4 million (2015: £0.1 million), which reflects the share of results of hVIVO’s investments in PrEP Biopharm Limited (£7.4 million loss) and Imutex Limited (£nil).

Administrative expense

Administrative expenses were £13.8 million (2015: £13.7 million). The increase is primarily due to non-capitalisable costs of investment in a medical management technology platform of £0.4 million, as well as increased spend on legal and professional fees, partially offset by savings achieved through the continuation of cost saving initiatives during the period. Administrative expense in 2016 included £1.1 million of leasehold provisions (2015: £1.0 million).

Taxation

The Group makes claims each year for research and development tax credits and, since it is loss-making, elects to surrender these tax credits for a cash rebate. The amount credited to the consolidated statement of comprehensive income with respect to amounts received and receivable for the surrender of research and development expenditure was £4.8 million for the year ended 31 December 2016 (2015: £3.7 million).

Consolidated statement of financial position

As of 31 December 2016 total assets less liabilities amounted to £46.1 million (2015: £63.6 million) including short-term deposits of £nil (2015: £37.0 million) and cash and cash equivalents of £25.7 million (2015: £14.2 million).

The principal movements in the consolidated statement of financial position during the year are summarised below:

- acquisition of equity in Imutex Limited of £7.1 million, inclusive of £0.1 million of transaction costs;
- recognition of losses (£7.4 million) and other comprehensive income (£0.2 million) relating to the Group's investment in PrEP Biopharm Limited;
- delivery of the licence of previously completed flu and asthma study data to PrEP Biopharm, resulting in a reduction of current intangible asset of £2.9 million;
- decrease in short-term deposits of £37.0 million;
- increase in cash and cash equivalents of £11.5 million; and
- decrease in current trade and other payables of £10.4 million, which includes the payment in January 2016 of £5.0 million deferred consideration in respect of the equity investment in PrEP Biopharm Limited on 1 November 2015.

Cash flow

The principal cash flows in the year were as follows:

Inflows

- finance income of £0.3 million (2015: £0.4 million).

Outflows

- cash outflow from operating activities of £17.8 million (2015: £9.8 million);
- equity investment in Imutex Limited of £7.1 million, inclusive of £0.1 million of transaction costs; and
- purchase of intangible assets (data management software platform) of £0.7m (2015: £nil).

Key performance indicators

The Directors consider the principal financial performance indicators of the Group to be:

- short-term deposits, cash and cash equivalents;
- revenue;
- gross profit;
- gross profit margin;
- research and development expense;
- administrative expense;
- share of loss of associates and joint ventures; and
- net profit or loss.

The Directors consider the principal non-financial performance indicators of the Group to be:

- performance of hVIVO's equity investments;
- collaboration opportunities with global pharmaceutical companies;
- development of intellectual property from our discovery research and product validation capabilities and, in particular, disease research (pathomics), data mining and analysis, sample collection and product testing processes;
- the expansion of the hVIVO platform and its increasing acceptance by global pharmaceutical companies and government bodies, including regulatory agencies;
- development of new human disease models; and
- research and development in other disease areas including asthma.

These elements are discussed within the Chief Executive Officer's statement.



Graham Yeatman

Chief Financial & Business Officer

19 April 2017

hVIVO plc

Consolidated Statement of Comprehensive Income

For the year ended 31 December 2016

	Note	2016 £'000	2015 £'000
Revenue		19,850	7,717
Cost of sales		(15,629)	(5,266)
Gross profit		4,221	2,451
Other income		276	1,187
Research and development expense		(6,282)	(10,199)
Provision against virus inventory	9	—	(1,617)
Administrative expense		(13,767)	(13,671)
Share of loss of associates and joint ventures	8	(7,371)	(146)
Loss from operations		(22,923)	(21,995)
Finance income		310	387
Finance costs		(18)	(17)
Loss before taxation		(22,631)	(21,625)
Taxation	3	4,750	3,716
Loss for the year		(17,881)	(17,909)
Other comprehensive income, net of tax			
Items that may be reclassified subsequently to profit or loss:			
Share of other comprehensive income of associates and joint ventures		207	(5)
Exchange differences arising on translating foreign operations		(65)	1
Total comprehensive loss for the year attributable to owners of the parent		(17,739)	(17,913)
Loss per share – basic (pence)	4	(22.9p)	(26.0p)
Loss per share – diluted (pence)	4	(22.9p)	(26.0p)

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 2016

	Note	2016 £'000	2015 £'000
Assets			
Non-current assets			
Goodwill	5	1,722	1,722
Intangible assets	6	3,375	3,030
Property, plant and equipment	7	1,552	2,679
Investment in associates and joint ventures	8	14,150	14,254
		20,799	21,685
Current assets			
Inventories	9	1,986	2,141
Current intangible asset	10	—	2,935
Trade and other receivables	11	3,704	2,642
Research and development tax credit receivable		4,558	4,101
Short-term deposits	12	—	37,031
Cash and cash equivalents	13	25,679	14,205
		35,927	63,055
Total assets		56,726	84,740
Equity and liabilities			
Equity			
Share capital		3,905	3,903
Share premium account		93,217	93,145
Share-based payment reserve		238	144
Merger reserve		4,199	4,199
Other reserve		211	211
Retained deficit		(55,718)	(37,979)
Total equity		46,052	63,623
Non-current liabilities			
Other payables	15	400	475
Provisions	16	3,131	3,140
		3,531	3,615
Current liabilities			
Trade and other payables	14	7,143	17,502
		7,143	17,502
Total liabilities		10,674	21,117
Total liabilities and equity		56,726	84,740

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 2016

	Share capital	Share premium account	Share-based payment reserve	Merger reserve	Other reserve	Retained deficit	Total equity
	£'000	£'000	£'000	£'000	£'000	£'000	£'000
As at 31 December 2014	3,383	72,498	249	4,199	921	(20,066)	61,184
Share-based payment	—	—	78	—	—	—	78
Proceeds from shares issued:							
Acquisition of subsidiary – settlement of deferred consideration	11	699	—	—	(710)	—	—
Exercise of warrants and share options	52	360	(183)	—	—	—	229
Issue of new shares	1	67	—	—	—	—	68
Placing net of related expenses	456	19,521	—	—	—	—	19,977
Total transactions with owners in their capacity as owners	520	20,647	(105)	—	(710)	—	20,352
Loss for the year	—	—	—	—	—	(17,909)	(17,909)
Exchange differences on translation of foreign assets	—	—	—	—	—	(4)	(4)
As at 31 December 2015	3,903	93,145	144	4,199	211	(37,979)	63,623
Share-based payment	—	—	94	—	—	—	94
Proceeds from shares issued:							
Issue of new shares	2	72	—	—	—	—	74
Total transactions with owners in their capacity as owners	2	72	94	—	—	—	168
Loss for the year	—	—	—	—	—	(17,881)	(17,881)
Share of other comprehensive income of associates and joint ventures	—	—	—	—	—	207	207
Exchange differences on translation of foreign assets	—	—	—	—	—	(65)	(65)
As at 31 December 2016	3,905	93,217	238	4,199	211	(55,718)	46,052

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 2016

		2016	2015
	Note	£'000	£'000
Net cash used in operating activities	17	(17,831)	(9,846)
Cash flows from investing activities			
Acquisition of intangible assets		(660)	(15)
Acquisition of property, plant and equipment		(162)	(869)
Decrease/(increase) in balances on short-term deposit		37,031	(9,024)
Investment in associates and joint ventures		(7,138)	(9,405)
Interest received		310	398
Net cash generated from/(used in) investing activities		29,381	(18,915)
Cash flows from financing activities			
Net proceeds from issue of shares		—	20,205
Other payables repaid		(75)	(75)
Net cash (used in)/generated from financing activities		(75)	20,130
Net increase/(decrease) in cash and cash equivalents		11,474	(8,631)
Exchange gain on cash and cash equivalents		—	10
Cash and cash equivalents at the start of year		14,205	22,826
Cash and cash equivalents at the end of year		25,679	14,205

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 2016 were approved by the Board of Directors on 19 April 2017. 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 2016 and year ended 31 December 2015.

The preliminary announcement is prepared on the same basis as set out in the statutory accounts for the year ended 31 December 2016. 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, as adopted by the European Union (EU) (IFRS), 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. The consolidated financial information of hVIVO plc is presented in pounds Sterling (£). The individual financial statements of hVIVO plc is presented in pounds Sterling (£) which is the Company's functional currency. For the purpose of the consolidated 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 2016 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 2016 the Group had short-term deposits, cash and cash equivalents of £25.7 million (2015: £51.2 million) and net current assets of £28.8 million (2015: £45.6 million).

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. The forecasts also include assumptions regarding the timing and quantum of investment in the Company's research and development programme. Whilst there are inherent uncertainties regarding the cash flows associated with the development of the hVIVO platform, together with the timing of signature and delivery of client engagements and future collaboration transactions, the Directors are satisfied that there is sufficient discretion and control as to the timing and quantum of cash outflows to ensure that the Company and Group are able to meet their liabilities as they fall due for the foreseeable future.

As part of its going concern review the Board has followed the guidelines published by the Financial Reporting Council entitled "Going Concern and Liquidity Risk Guidance for UK Companies 2009". 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 the Consolidated Financial Statements.

2. Segmental information

The Group's Chief Operating Decision Maker, 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".

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 is derived from activities undertaken in the UK.

During the year ended 31 December 2016 the Group had four customers who each generated revenue greater than 10% of total revenue (2015: two customers). These customers generated 49%, 24%, 14% and 11% of revenue (2015: 59% and 28% of revenue).

3. Taxation

	Year ended	Year ended
	31 December	31 December
	2016	2015
	£'000	£'000
Current tax:		
Current year research and development tax credit	(4,293)	(3,749)
Adjustments in respect of previous periods	(473)	31
Foreign current tax	16	2
Deferred tax:		
Origination and reversal of temporary timing differences	—	—
	(4,750)	(3,716)
Corporation tax is calculated at 20% (2015: 20.25%) 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:		
Loss before taxation	(22,631)	(21,625)
Tax at the UK corporation tax rate of 20% (2015: 20.25%)	(4,526)	(4,379)
Expenses not deductible in determining taxable profit	18	129
Income not taxable for tax purposes	—	(595)
Fixed asset temporary differences not recognised	7	8
Current year research and development tax credit	(1,681)	(1,542)
Movement in unrecognised deferred tax asset	1,524	2,137
Other temporary timing differences not recognised	381	495
Adjustments in respect of prior periods	(473)	31
Tax for the year	(4,750)	(3,716)

Factors affecting current and future taxation

The rate of UK corporation tax during the year was 20%. It will fall to 19% from 1 April 2017, and 17% from 2020.

As at 31 December 2016, the Group had tax losses available for carry forward of approximately £22.6 million (2015: £22.8 million). The Group has not recognised deferred tax assets of £3.9 million (2015: £4.1 million) relating to carried forward losses. 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 in the short term 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.

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	Year ended
	31 December	31 December
	2016	2015
	£'000	£'000
Earnings		
Loss for the year	(17,881)	(17,909)
Number of shares		
Weighted average number of ordinary shares for the purposes of basic EPS	78,076,407	68,943,581
Effect of dilutive potential ordinary shares:		
– share options	—	—
Weighted average number of ordinary shares for the purposes of diluted EPS	78,076,407	68,943,581

5. Goodwill

	31 December	31 December
	2016	2015
	£'000	£'000
At 1 January	1,722	1,722
Recognised on acquisition of subsidiary	—	—
At 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 our 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. As at 31 December 2016, the recoverable amount of the cash generating unit was considered to be significantly in excess of its book value.

6. Intangible assets

	Acquired Intellectual property £'000	Capitalised Software Development £'000	Total £'000
Cost:			
At 31 December 2014	2,118	1,228	3,346
Additions at cost	—	15	15
Disposals	—	—	—
At 31 December 2015	2,118	1,243	3,361
Additions at cost	—	660	660
Disposals	—	—	—
At 31 December 2016	2,118	1,903	4,021
Accumulated depreciation:			
At 31 December 2014	—	13	13
Charge for the year	283	35	318
Disposals	—	—	—
At 31 December 2015	283	48	331
Charge for the year	282	33	315
Disposals	—	—	—
At 31 December 2016	565	81	646
Carrying amount:			
At 31 December 2014	2,118	1,215	3,333
At 31 December 2015	1,835	1,195	3,030
At 31 December 2016	1,553	1,822	3,375

The useful lives of assets for amortisation range from five to ten years.

7. Property, plant and equipment

	Leasehold improvements £'000	Plant and machinery £'000	Computer equipment £'000	Total £'000
Cost:				
At 31 December 2014	2,419	2,990	1,045	6,454
Additions	72	655	142	869
Disposals	—	(2)	—	(2)
At 31 December 2015	2,491	3,643	1,187	7,321
Additions	21	75	66	162
Disposals	—	—	—	—
At 31 December 2016	2,512	3,718	1,253	7,483
Accumulated depreciation:				
At 31 December 2014	1,347	1,361	593	3,301
Charge for the year	320	729	293	1,342
Disposals	—	(1)	—	(1)
At 31 December 2015	1,667	2,089	886	4,642
Charge for the year	334	750	204	1,288
Disposals	—	—	—	—
At 31 December 2016	2,001	2,839	1,090	5,930
Carrying amount:				
At 31 December 2014	1,072	1,629	452	3,153
At 31 December 2015	824	1,554	301	2,679
At 31 December 2016	511	879	163	1,553

8. Investment in associates and joint ventures

PrEP Biopharm Limited

On 1 November 2015 the Company acquired 62.62% of the share capital of PrEP Biopharm Limited for cash consideration of £14.0 million, of which £5.0 million was deferred consideration at 31 December 2015 and paid in January 2016. Acquisition costs of £0.4 million have been capitalised as part of the cost of the investment. PrEP Biopharm Limited is a UK-based development stage biopharmaceutical company which is developing infectious disease products. At the same time as the investment, PrEP Biopharm Limited entered into contractual arrangements with hVIVO Services Limited to the value of £10.0 million.

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

	2016	2015
	£'000	£'000
As at 1 January	14,254	—
Additions	—	14,405
Share of loss after tax recognised in the consolidated statement of comprehensive income	(7,371)	(146)
Share of other comprehensive income/(loss) of associates and joint ventures	129	(5)
As at 31 December	7,012	14,254

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	31 December
	2016	2015
	£'000	£'000
Current assets	3,962	15,298
Non-current assets	5,090	5,076
Current liabilities	(369)	(123)
Net assets	8,683	20,251
Interest in the associate	5,437	12,681
Goodwill	1,573	1,573
Carrying amount of the Group's interest in the associate	7,010	14,254

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

Its loss of £11.6 million (2015: £0.3 million) for the year ended 31 December 2016 consisted of £11.6 million of research and development expenditure (2015: £0.2 million) and £1.1 million of administrative expenditure (2015: £0.1 million), partially offset by income in respect of a research and development tax credit refund claim and foreign exchange gains.

Imutex Limited

On 21 April 2016, the Company acquired 49.0% of the share capital of Imutex Limited for £7.0 million consideration under the terms of a Joint Venture Agreement with PepTcell Limited. Acquisition costs of £0.2 million have been capitalised as part of the investment. Imutex Limited is a UK-based company developing vaccines against influenza and mosquito borne diseases. At the same time as the investment, PepTcell Limited entered into a contractual arrangement with hVIVO Services Limited for a FLU-v clinical study to the value of £5.5 million.

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

	2016
	£'000
As at 1 January	—
Additions	7,138
Share of loss after tax recognised in the consolidated statement of comprehensive income	—
As at 31 December	7,138

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

	31 December
	2016
	£'000
Current assets	383
Non-current assets	14,247
Current liabilities	(383)
Net assets	14,247
Interest in the joint venture	6,981
Goodwill	158
Carrying amount of the Group's interest in the joint venture	7,139

Imutex Limited generated no revenues during the period as the activity was that of product development.

It recorded a loss of £nil for the period ended 31 December 2016.

9. Inventories

	31 December	31 December
	2016	2015
	£'000	£'000
Laboratory and clinical consumables	35	33
Virus – finished goods	1,952	2,108
	1,986	2,141

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 2015 a provision of £1,614,000 was recognised against the carrying value of "Virus – finished goods". During 2013 to 2014 hVIVO developed two separate strains of H3N2 flu virus for use in both client, equity investment and internal studies. Two strains were developed in order to mitigate the scientific and manufacturing risk of one strain failing development and to ensure that at least one strain was successful in the timeframe. As it is likely that only one of these strains will be used in client studies going forward, the second strain has been fully provided against.

No additional provision was recognised during 2016.

10. Current intangible asset

	31 December	31 December
	2016	2015
	£'000	£'000
At 1 January	2,935	—
Additions at cost	3,475	2,935
Recognised during the year	(6,410)	—
At 31 December	—	2,935

During 2015 hVIVO commenced the PrEP-001 flu and asthma clinical studies with a view to the study data generating future economic benefit through potential licensing arrangements. Accordingly, the costs of performing these studies were capitalised. On 1 November 2015, PrEP Biopharm Limited contracted to licence the study data for the flu and asthma studies. The study data was completed and provided to PrEP Biopharm Limited during 2016, at which point these costs were transferred to cost of sales.

11. Trade and other receivables

	31 December	31 December
	2016	2015
	£'000	£'000
Trade receivables	1,001	551
VAT recoverable	260	—
Other receivables	399	405
Prepayments	1,343	1,274
Accrued income	701	412
	3,704	2,642

12. Short-term deposits

	31 December	31 December
	2016	2015
	£'000	£'000
Short-term deposits	—	37,031

Balances held on short-term deposits have maturity dates between three and twelve months at the time of investment.

13. Cash and cash equivalents

	31 December	31 December
	2016	2015
	£'000	£'000
Cash at bank and in hand	25,679	14,205

14. Trade and other payables

	31 December	31 December
	2016	2015
	£'000	£'000
Trade payables	2,204	2,265
Other taxes and social security	327	382
VAT payable	—	984
Other payables	178	5,134
Accruals	1,370	1,303
Deferred income	3,064	7,434
	7,143	17,502

15. Other payables

	31 December	31 December
	2016	2015
	£'000	£'000
Amounts to be settled beyond one year	400	475

On 11 March 2013, the Group signed an Agreement for Lease with Queen Mary BioEnterprises Limited to develop the third floor of the QMB Innovation Centre with a five-year term and an option to extend for another five years. As part of the agreement, QMB advanced the Group a repayable interest-free lease incentive of £750,000 to develop the third floor, with £75,000 per annum repayable over a ten-year period. The lease incentive is recognised as a liability. In the event that the Group does not exercise its option to extend the lease agreement for another five years, the remaining unpaid principal of the advance (£375,000) must be repaid at the end of the five-year contractual lease term.

16. Provisions

	Onerous lease provision	Dilapidations provision	Total
	£'000	£'000	£'000
At 1 January 2016	3,000	140	3,140
Additional provision in the year	1,037	—	1,037
Used during the year	(1,046)	—	(1,046)
At 31 December 2016	2,991	140	3,131

Onerous lease provision of £3.0 million (31 December 2015: £3.0 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 the lease as negotiations will involve third parties. The provision is expected to be used between 2017 and 2019. Total expected costs to be incurred are £3.0 million.

Buildings dilapidations of £140,000 (31 December 2015: £140,000) represent the present value of costs to be incurred for the restoration of premises occupied by the Group. The provision is expected to be used during 2018. Total expected costs to be incurred are £140,000.

17. Note to the consolidated statement of cash flows

	Year ended	Year ended
	31 December	31 December
	2016	2015
	£'000	£'000
Cash flow from operating activities		
Loss before income tax	(22,631)	(21,625)
Adjustments for:		
Share of loss of associates and joint ventures	7,371	146
Depreciation of property, plant and equipment	1,288	1,342
Amortisation of intangible assets	315	318
Payment of Non-Executive Director fees by issue of shares	74	68
Share-based payment expense	94	78
Finance costs	18	17
Finance income	(310)	(387)
Loss/(gain) on foreign exchange	—	(8)
RDEC credit included in other income	(267)	(352)
(Decrease)/increase in provisions	(9)	10
Changes in working capital:		
Decrease in inventories	155	1,590
Decrease/(increase) in current intangible asset	2,935	(2,935)
(Increase)/decrease in trade and other receivables	(1,062)	249
(Decrease)/increase in trade and other payables	(10,359)	7,885
Cash used in operations	(22,388)	(13,604)
Finance costs	(18)	(17)
Income tax refund	4,575	3,775
Net cash used in operating activities	(17,831)	(9,846)

As at 31 December 2016, a £267,000 (31 December 2015: £352,000) asset has been recognised in respect of a Research and Development Expenditure Credit. This amount is presented within the research and development tax credit receivable section in the consolidated statement of financial position. The remaining tax credit is presented below loss from operations in the consolidated statement of comprehensive income.