Registered number: 08008725

# hVIVO plc

HALF-YEAR FINANCIAL REPORT

for the six months ended 30 June 2018

#### **Executive Chairman's Statement**

#### Introduction

It has been a period of steady progress for hVIVO as we execute on our long-term growth strategy, focussing on our core fee-for-service challenge study services in clinical development in airways diseases.

#### Unique market opportunity in human challenge studies

Encouragingly we are currently negotiating a high number of contracts which if completed will add to the pipeline for Q4 2018 and beyond, exemplified by the recent contract signing, post period end in September, for work to a contract value of £11.9 million.

The concept of human challenge studies is not new, but the use of human challenge studies, as proof-of-concept studies, is continuing to gain wider acceptance in viral diseases such as influenza (flu) and respiratory syncytial virus (RSV). Leading the way in these areas, hVIVO is now experiencing significant interest in expanding the concept into product development for airways diseases such as asthma, chronic obstructive pulmonary disease (COPD) and cough, where cost, time and risks associated with achieving clinical proof of concept are considerable. These opportunities provide valuable and exciting opportunities to expand our services and increase our revenues. The human challenge model has many advantages to meet the increasing pressures on clinical development and has the ability to:

- Provide early proof of concept efficacy data for candidate selection
- Enable accelerated development of pipeline compounds, through early identification of endpoints
- Effectively translate animal data to human endpoints and to relate healthy volunteer data to field outcome
- Require clinical studies with relatively small numbers of subjects, hence lower time and cost, to achieve clinical proof-of-concept
- Lower the subsequent risk of negative outcomes when performing large field-based Phase II and III studies, given that the early detection of efficacy and identification of endpoints can strengthen protocol design and patient selection in the later phase studies

As well as continuing to satisfy the needs of our existing clients through a commitment to a high standard of service delivery, we continually look at improving our marketing and business development process to ensure we promote our services to a diverse range of companies. As a result, the Company is currently engaged in a number of discussions with companies for contracting studies across the entire range of our challenge portfolio (including allergen, human rhinovirus (HRV), flu and RSV). The Company's current contracted pipeline is experiencing strong demand for RSV challenge studies and there are further opportunities in RSV that the Company is expecting to sign in the near term. There are currently no effective drugs approved for RSV and the risks of RSV infections are high in children, the elderly and immunocompromised patients. hVIVO's world leading RSV-human challenge model has been demonstrated to be robust and reproducible. Since hVIVO established its RSV model over a decade ago, it has inoculated over 1000 volunteers.

#### Infrastructure

It is important that we invest in our systems and processes, our facilities and our people, ensuring these investments support our service offerings and long-term growth aspirations. To enable this ongoing investment, we intend to drive revenue growth with a commitment to operational efficiency and cost containment by focusing on core activities and how we undertake them across the business. This will continue to be a focus for the remainder of 2018 and into 2019, as we strive for operational excellence throughout the Company. The majority of the financial benefit of this will be recognised in 2019 and beyond.

#### **Operational Review**

#### Progress across contracted pipeline

#### Human challenge studies

The Company has conducted human challenge studies for multiple clients, both large pharmaceutical and biotech and in a range of challenge models using differing virus challenge agents. Post period end in September, we were pleased to sign another large study.

#### Initiation of a novel cough model study using human rhinovirus (HRV)

Acute cough is a common condition, most often due to an acute viral upper respiratory tract infection (URTI) and to-date there are no approved targeted medications to treat the underlying mechanism of cough. hVIVO is currently collaborating with a leading global pharmaceutical company to leverage hVIVO's HRV experimental model in healthy volunteers in order to expand efficacy findings of their breakthrough first in class chronic cough treatment to the general population during a common cold infection. This represents the first time that objective cough measurements have been used as a primary endpoint in an experimental virus model.

In addition and separate to this study, we have also analysed over 100 subject reports of cough symptoms within our HRV, RSV and Flu challenge models hVIVO presented this work at the European Respiratory Conference in Paris this week with a view to displaying the profile and pattern of cough in our models and their possible utility for companies with chronic cough compounds that want to possibly expand their label into acute cough.

#### **US Government agency collaboration – DARPA**

Good progress has been made on the flu contagiousness project, with cost-sharing grant with the US Defense Advanced Research Projects Agency (DARPA) via its Prometheus programme, that is due to complete by the end of 2018.

The Prometheus program aims to discover methods of determining whether an individual is contagious before exhibiting symptoms of illness. Such an approach has the potential to improve the forecasting of infectious disease outbreaks, reduce the risk of deploying contagious military personnel and inform border control during pandemic outbreaks.

In the first half of 2018, the Company successfully concluded the clinical phase of the flu contagiousness challenge study and the results were delivered to DARPA. The Company initiated data analytics work with DARPA to generate an algorithm to predict contagiousness. The results of the analytics work will be delivered to DARPA when the project completes at the end of the year.

The costs associated with this project are reported as R&D expense and the grant income as Other Income.

#### Alliances/Joint ventures

#### Imutex Limited (Joint venture) - Assets progress

Imutex Limited (Imutex), hVIVO's 49% 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. The positive results from two Phase IIb studies have shown the desired immunological and efficacy responses and have instructed us as to which endpoints to proceed with for the Phase III studies subject to discussion with regulatory authorities. Based on this data, management believe FLU-v is now ready for Phase III development. 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 003, Phase IIb field study

In June 2018, the Company reported positive final results from a Phase IIb field study of FLU-v for the treatment of flu.

The study was a randomised, double-blind, placebo-controlled, single-centre trial part of the EU-funded Universal Influenza Vaccines Secured Consortium (UNISEC) project, to assess the immunogenicity, safety and exploratory efficacy of two different formulations and dosing regimens of FLU-v vaccine administered in healthy adults. In this trial, 176 subjects (aged 18-60 years) were assigned to either placebo or treatment arms.

The study results showed:

- Statistical significance in key immune indicators, an 83% reduction in severe flu and better than placebo in all other efficacy endpoints
- Primary and secondary endpoints achieved with induction of long-lasting T and B cell immunological responses
- Numerical reduction in flu infection rates and severity and duration of symptoms observed (study not powered for statistical significance in infection/symptoms)
- Treatment with FLU-v was well tolerated with an adverse event profile consistent with earlier studies

#### FLU-v 004, Phase IIb viral challenge study

In March 2018, the Company reported initial results from a Phase IIb clinical human challenge study of FLU-v for the treatment of flu.

FLU-v 004 was a challenge study conducted by hVIVO using the National Institute of Allergy and Infectious Diseases (NIAID) virus, methods and analysis as a result of a collaboration between SEEK and the NIAID, part of the US National Institutes of Health (NIH).

The study was a randomised, double-blind, placebo-controlled single-centre trial to assess the efficacy and safety of two different formulation and dosing regimens of the FLU-v vaccine, administered in healthy adults. In this trial, 123 subjects (aged 18-60 years) were assigned to either placebo or treatment arms.

#### The study results showed:

Statistical significance in reduction in number of people with two or more symptoms

In June 2018 the Company communicated that further analysis of data by the NIAID (relating to the primary end-point, that to date has not been met) was ongoing and that results would be available soon. The NIAID is a large academic body and prides itself on its independence and whilst the Company believed the results would be forthcoming sooner, the final results of this study will be published by the NIAID in due course under their publication strategy.

The further data analysis has no impact for a Phase III study as the efficacy data that is needed has been achieved from the two FLU-v Phase IIb studies.

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

A Phase I, first-in-man study conducted at NIAID, began in early 2017 and results are expected in by end 2018.

As previously announced, the Board of Imutex is exploring strategic alternatives with regards to both assets, including but not limited to a full sale, a licensing agreement or a non-dilutive funding arrangement with a collaborator to run the Phase III development and study for the FLU-v vaccine candidate. Any material information regarding discussions or about the Imutex assets will be announced as appropriate.

# PrEP Biopharm Limited (Associate) - Asset update

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

The management of PrEP Biopharm continue to plan for the future development of PrEP-001, a broad spectrum anti-viral treatment/ prophylaxis development stage asset and are in active discussion with potential investors and partners in order to progress the development of the product.

PrEP-001 is a novel, nasally administered, broad-spectrum agent designed to leverage the body's innate immune system to prevent respiratory tract viral infections. hVIVO has previously reported positive proof-of-concept challenge studies in healthy volunteers challenged with flu and human rhinovirus 16, HRV-16 (common cold). Results of these studies were published in early 2018 in the peer reviewed journal Antiviral Research.

#### Driving operational excellence with cost efficiency

To reduce costs and improve operational excellence, a number of initiatives are underway that are in line with our focus on our core fee-for-service challenge study services. The main cost base reduction is primarily focussed on headcount savings. Subsequent to the end of the financial period we announced that we will cease our research & discovery activities and we recently commenced a redundancy consultation process with affected employees. This will result in the closure of our scientific research facility in Welwyn, UK and the rationalising of our operations into the Company's main site in London. We will focus any research efforts on targeted programmes designed to support our core service offerings. Other initiatives, including evaluating processes and cost saving exercises, are ongoing.

#### **Board change**

The Company also announces today that Graham Yeatman has decided to step down from his position as Chief Financial & Business Officer and will leave the Board at the end of December 2018 at which time the Board composition will be adjusted.

Graham joined Retroscreen Virology Limited (previous company name) as Finance Director in May 2011, prior to its IPO and listing on the AIM market of the London Stock Exchange in May 2012. He subsequently became Chief Financial & Business Officer in January 2015.

Shelley Fraser, currently Vice President, Finance, will become Finance Director with immediate effect. Shelley joined hVIVO two years ago and has 18 years finance experience across several pharmaceutical, biotech and life sciences companies. She will work closely with Graham in the period up to his departure to ensure a smooth transition and responsibility for the financial management of the Company. Shelley will also assume the role of Company Secretary from 1 January 2019.

#### **Financial Review**

#### Condensed Consolidated Statement of Comprehensive Income

Revenue for the six months ended 30 June 2018 was £4.9 million (H1 2017: £3.9 million; 2017: £10.9 million), and gross profit was £1.2 million (H1 2017: £1.0 million; 2017: £3.6 million), from client challenge studies completing in H1 2018. We enter the second half of the year with higher utilisation of the quarantine unit from new client engagements and a growing sales pipeline that is showing signs of converting into a strong contracted pipeline expected to enter the quarantine unit from 2019.

Other income was £1.5 million (H1 2017: £0.1m; 2017: £1.5 million) and includes cost share from DARPA in respect of our flu contagiousness project of £1.4 million (H1 2017: £nil; 2017: £1.3 million).

Research and development expense was £2.8 million (H1 2017: £2.8 million; 2017: £6.1 million) from spend focused on completing a smaller number of previously initiated projects. This expense includes costs of £1.3 million (H1 2017: £1.1 million; 2017: £2.8 million) that are covered by the flu contagiousness grant from DARPA of £1.4m that is reported in Other Income.

Administrative expense was £4.9 million (H1 2017: £6.1 million; 2017: £11.4 million). The £1.2 million (19.1%) reduction has been achieved through the continuation of process efficiencies and cost savings initiatives and we expect the full year administrative expense to reduce further as more cost savings, already initiated, are realised.

The share of the loss of associate was £0.4 million (H1 2017: £0.6 million; 2017: £1.6 million), which reflects the share of results of hVIVO's investments in PrEP Biopharm and Imutex. This has reduced year-on-year due to the lower spend of both PrEP Biopharm and Imutex following completion of the PrEP-001 and FLU-v challenge studies in 2017, which were conducted by hVIVO Services Limited.

Loss before taxation was £5.3 million (H1 2017: £9.1 million; 2017: £14.8 million).

#### Condensed Consolidated Statements of Financial Position and Cash Flows

As at 30 June 2018, net assets amounted to £29.3 million (H1 2017: £38.4 million; 2017: £33.4 million), including cash and cash equivalents of £10.7 million (H1 2017: £15.4 million; 2017: £20.3 million). A R&D tax credit refund of £2.5 million was received from HM Revenue & Customs on 11 July 2018.

Net cash used in operating activities over the six months to 30 June 2018 was £9.5 million (H1 2017: £10.1 million; 2017: £5.1 million).

#### Summary and outlook

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

With the changes to our structure, our R&D spend for 2019 will reduce significantly compared to this year. A more disciplined approach to capital allocation will be taken going forward, focussed specifically on opportunities to support the enhancement of our development services. However, it will not be until 2019 that we will really start to see the full benefit of these changes.

While the Board's expectations remain unchanged for the full year, we do expect to have a higher level of sales for the second half of the year compared to the first half. We also enter the second half of 2018 with the strongest potential sales pipeline we have had for several years and a growing number of sales leads that we are hopeful of converting into a book of contracted work from Q4 2018 and throughout 2019. Indeed, we only need to sign a couple of the current, highly probably, study contracts before the end of the year for most of next year's quarantine capacity to be filled before 2019 begins.

**Dr Trevor Phillips**Executive Chairman
19 September 2018

**hVIVO plc**Condensed Consolidated Statement of Comprehensive Income
For the six months ended 30 June 2018

		6 months ended	6 months ended	Year ended
		30 June	30 June	31 December
		2018	2017	2017
		Unaudited	Unaudited	Audited
	Note	£'000	£'000	£'000
Revenue from contracts with customers	2	4,850	3,924	10,878
Cost of sales		(3,687)	(2,920)	(7,316)
Gross profit		1,163	1,004	3,562
Other income		1,520	95	1,455
Research and development expense		(2,762)	(2,817)	(6,059)
Administrative expense		(4,902)	(6,063)	(11,379)
Loss on provision of services to joint ventures	4	-	(744)	(800)
Share of loss of associates and joint ventures	5	(362)	(606)	(1,613)
Loss from operations		(5,343)	(9,131)	(14,834)
Finance income		30	42	71
Finance costs		(27)	(27)	(54)
Loss before taxation		(5,340)	(9,116)	(14,817)
Taxation	6	922	1,393	1,934
Loss for the period		(4,418)	(7,723)	(12,883)
Other comprehensive income, net of tax				
Items that may be reclassified subsequently to profit or l	oss			
Share of other comprehensive income of associates and joventures	oint	47	(21)	16
Exchange differences arising on translating foreign operation	ions	4	(8)	(11)
Total comprehensive loss for the period attributable to o the parent	wners of	(4,367)	(7,752)	(12,878)
Loss per share - basic (pence)	7	(5.6p)	(9.9p)	(16.5p)
Loss per share - diluted (pence)	7	(5.6p)	(9.9p)	(16.5p)

All results derive from continuing operations.

The accompanying notes are an integral part of the Condensed Consolidated Statement of Comprehensive Income.

# **hVIVO plc**Condensed Consolidated Statement of Financial Position As at 30 June 2018

	Note	30 June 2018 Unaudited £'000	Restated 30 June 2017 Unaudited £'000	Restated 31 December 2017 Audited £'000
Assets				
Non-current assets				
Goodwill		1,722	1,722	1,722
Intangible assets		3,131	3,411	3,232
Property, plant and equipment		378	936	535
Investment in associates and joint ventures	8	12,238	13,522	12,553
		17,469	19,591	18,042
Current assets				
Inventories		1,553	1,978	1,742
Trade and other receivables	9	2,105	3,043	1,771
Contract assets	10	13	17	417
Research and development tax credit receivable		3,686	6,031	2,625
Short-term deposits		-	5,000	-
Cash and cash equivalents		10,693	10,355	20,289
		18,050	26,424	26,844
Total assets		35,519	46,015	44,886
Equity and liabilities				
Equity				
Share capital		3,911	3,906	3,909
Share premium account		93,310	93,256	93,290
Other reserve		211	211	211
Share-based payment reserve		637	286	382
Merger reserve		4,199	4,199	4,199
Retained deficit		(72,963)	(63,470)	(68,596)
Total equity		29,305	38,388	33,395
Non-current liabilities		·	•	·
Other payables		_	363	_
Provisions		1,608	2,925	2,280
		1,608	3,288	2,280
Current liabilities		,	-,	,
Trade and other payables	11	2,393	3,041	3,365
Contract liabilities	12	2,213	1,298	5,846
		4,606	4,339	9,211
Total liabilities		6,214	7,627	11,491
Total liabilities and equity		35,519	46,015	44,886
Total habilities and equity		33,313	+0,013	44,000

The accompanying notes are an integral part of the Condensed Consolidated Statement of Financial Position.

The Condensed Consolidated Interim Financial Statements of hVIVO plc (registered company number 08008725) were approved by the Board of Directors and authorised for issue on 19 September 2018 and signed on its behalf by:

**Graham Yeatman** 

Chief Financial & Business Officer

**hVIVO plc**Condensed Consolidated Statement of Changes in Equity
As at 30 June 2018

			Share-				
		Share	based				
	Share	premium	payment	Merger	Other	Retained	Total
	capital	account	reserve	reserve	reserve	deficit	equity
	£'000	£'000	£'000	£'000	£'000	£'000	£'000
As at 1 January 2017	3,905	93,217	238	4,199	211	(55,718)	46,052
Share-based payments	-	-	144	-	-	-	144
Proceeds from shares issued:							
Issue of new shares	4	73	-	-	-	-	77
Total transactions with owners in their	4	73	144	-	-	-	221
capacity as owners							
Loss for the year	-	-	-	-	-	(12,883)	(12,883)
Share of other comprehensive income of associates and joint ventures	-	-	-	-	-	16	16
Total comprehensive income	4	73	144	-	-	(12,867)	(12,646)
Exchange differences on translation of	-	-	-	-	-	(11)	(11)
foreign assets							
As at 31 December 2017	3,909	93,290	382	4,199	211	(68,596)	33,395
Loss for the period	-	-	-	-	-	(4,418)	(4,418)
Other comprehensive income	-	-	-	-	-	51	51
Total comprehensive income	-	-	-	-	-	(4,367)	(4,367)
Issue of new shares	2	20	-	-	-	-	22
Share-based payments	-	-	255	-	-	-	255
As at 30 June 2018	3,911	93,310	637	4,199	211	(72,963)	29,305
As at 1 January 2017	3,905	93,217	238	4,199	211	(55,718)	46,052
Loss for the period	-	-	-	-	-	(7,723)	(7,723)
Other comprehensive income	-	-	-	-	-	(29)	(29)
Total comprehensive income	-	-	-	-	-	(7,752)	(7,752)
Issue of new shares	1	39	-	-	-	-	40
Share-based payments		-	48	-	-		48
As at 30 June 2017	3,906	93,256	286	4,199	211	(63,470)	38,388

The accompanying notes are an integral part of the Condensed Consolidated Statement of Changes in Equity.

**hVIVO plc**Condensed Consolidated Statement of Cash Flows
For the six months ended 30 June 2018

		6 months ended	6 months ended	Year ended
		30 June	30 June	31 December
		2018	2017	2017
		Unaudited	Unaudited	Audited
		£'000	£'000	£'000
Net cash used in operating activities	14	(9,514)	(10,092)	(5,065)
Cash flows from investing activities				
Acquisition of intangible assets		(89)	(194)	(271)
Acquisition of property, plant and equipment		(23)	(38)	(50)
Increase in balances on short-term deposit		-	(5,000)	-
Interest received		30	42	71
Net cash used in investing activities		(82)	(5,190)	(250)
Cash flows from financing activities				
Other payables repaid		-	(37)	(75)
Net cash used in financing activities		-	(37)	(75)
Net decrease in cash and cash equivalents		(9,596)	(15,319)	(5,390)
Exchange loss on cash and cash equivalents		-	(5)	-
Cash and cash equivalents at the start of financial period		20,289	25,679	25,679
Cash and cash equivalents at the end of financial period		10,693	10,355	20,289

The accompanying notes are an integral part of the Condensed Consolidated Statement of Cash Flows.

#### Notes to the Condensed Consolidated Interim Financial Statements

#### 1. Accounting policies

#### Basis of preparation and approval of the Interim Financial Statements

The accounting policies adopted in the preparation of the Interim Financial Statements are consistent with those set out in the Group's Annual Report and Financial Statements 2017, which were prepared in accordance with International Financial Reporting Standards ("IFRS") as adopted by the European Union and as issued by the International Accounting Standards Board ("IASB"), and are expected to be consistent with the accounting policies that will be applied in the Group's Annual Report and Financial Statements 2018. They are prepared in accordance with IAS 34, "Interim Financial Reporting".

The Interim Financial Statements for the six months ended 30 June 2018 do not include all the information required for full Annual Financial Statements and should be read in conjunction with the Consolidated Financial Statements for the year ended 31 December 2017. The financial information for the six months ended 30 June 2018 and for the six months ended 30 June 2017 is unaudited.

The Interim Financial Statements do not comprise statutory accounts within the meaning of Section 434 of the Companies Act 2006. Statutory accounts for the year ended 31 December 2017 were approved by the Board on 18 April 2018 and delivered to the Registrar of Companies. The report of the auditors on those accounts was unqualified, did not contain an emphasis of matter paragraph and did not contain any statement under Section 498(2) or Section 498(3) of the Companies Act 2006.

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 Group's research and development programme. The Directors are satisfied that there is sufficient discretion and control as to the timing and quantum of cash outflows to ensure that the Group will meet its liabilities as they fall due for the foreseeable future. The Directors have a reasonable expectation that the 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 Interim Financial Statements.

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 Group Financial Statements are presented in pounds Sterling (£), which is the Group's presentational currency, and all values are rounded to the nearest thousand (£'000) except where indicated otherwise.

The Interim Financial Statements were approved by the Board of Directors on 19 September 2018.

#### Notes to the Condensed Consolidated Interim Financial Statements

#### 2. New standards, interpretations and amendments adopted by the Group

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

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

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

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

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

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

The Group adopted IFRS 15 using the full retrospective method of adoption. The effect of this is as follows:

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

	Adjustments		
	6 Months ended	Year ended	
	30 Jun 2017	31 Dec 2017	
	£'000	£'000	
Assets			
Trade and other receivables	(13)	(17)	
Contract assets	13	17	
Total assets	-	-	
Liabilities			
Trade and other payables	(2,213)	(1,298)	
Contract liabilities	2,213	1,298	
Total liabilities	-	-	

#### Service revenues

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

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

#### Notes to the Condensed Consolidated Interim Financial Statements

The statement of financial position as at 31 December 2017 was restated, resulting in: recognition of Contract assets amounting to £17,000, and decrease in Trade and other receivables amounting to £17,000.

#### Advances received from customers

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

Reclassifications have been made from deferred revenue to Contract liabilities for the outstanding balance of advances from customers. The statement of financial position as at 31 December 2017 was restated, resulting in: increases in current and non-current portions of Contract liabilities amounting to £1,298,000 and £nil, respectively; decreases in current and non-current portions of Deferred revenue amounting to £1,298,000, and £nil, respectively; and decrease in retained earnings amounting to £nil.

## Presentation and disclosure requirements

As required for the Condensed Consolidated Interim Financial Statements, the Group disaggregated revenue recognised from contracts with customers into categories that depict how the nature, amount, timing and uncertainty of revenue and cash flows are affected by economic factors. The Group also disclosed information about the relationship between the disclosure of disaggregated revenue and revenue information disclosed for each reportable segment. Refer to Note 3 for the disclosure on disaggregated revenue.

#### b. IFRS 9 Financial Instruments

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

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

#### Classification and measurement

Except for certain trade receivables, under IFRS 9, the Group initially measures a financial asset at its fair value plus, in the case of a financial asset not at fair value through profit or loss, transaction costs.

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

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

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

#### Notes to the Condensed Consolidated Interim Financial Statements

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

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

#### <u>Impairment</u>

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

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

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

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

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

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

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

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

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

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

## Notes to the Condensed Consolidated Interim Financial Statements

#### 3. Revenue from contracts with customers and segmental information

The Group's Chief Operating Decision Maker, the Executive Chairman, is responsible for resource allocation and the assessment of performance. In the performance of this role, the Executive Chairman 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 services".

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

# 4. Loss on provision of services to joint ventures

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

#### 5. Share of loss of associates and joint ventures

hVIVO plc holds equity investments in development stage biopharmaceutical companies. As the invested companies are incurring expenditure to develop products no revenue will be generated, and losses will be presented, until the products are successfully developed.

At 30 June 2018, the Group held an investment in one associate, PrEP Biopharm Limited, and one joint venture, Imutex Limited (see Note 8).

The Group's share of after tax losses of associates and joint ventures is set out below:

	6 Months ended	6 Months ended	Year ended
	30 Jun 2018	30 Jun 2017	31 Dec 2017
	Unaudited £'000	Unaudited £'000	Audited £'000
Share of loss of associate and joint venture	(362)	(606)	(1,613)
Share of comprehensive income/(loss)	47	(21)	16
Share of total comprehensive income	(315)	(627)	(1,597)

Summarised combined income statement information in respect of PrEP Biopharm Limited and Imutex Limited is set out below:

	6 Months ended	6 Months ended	Year ended
	30 Jun 2018	30 Jun 2017	31 Dec 2017
	Unaudited	Unaudited	Audited
	£'000	£'000	£'000
Revenue	-	-	_
R&D Expenditure	(534)	(1,429)	(3,807)
Loss after taxation	(593)	(1,765)	(3,357)
Other comprehensive income	(5)	(108)	(39)
Total comprehensive income	(598)	(1,873)	(3,396)

# Notes to the Condensed Consolidated Interim Financial Statements

#### 6. Taxation

	6 Months ended	6 Months ended	Year ended
	30 Jun 2018	30 Jun 2017	31 Dec 2017
	Unaudited	Unaudited	Audited
	£'000	£'000	£'000
Tax Benefit:			
R&D tax credit	(934)	(1,459)	(2,261)
Adjustments in respect of prior periods	5	28	285
Foreign current tax charge	7	38	42
	(922)	(1,393)	(1,934)

The Group continues to account for its recurring annual SME R&D tax credit as an income tax benefit due to the requirement to surrender tax losses in exchange for recoverable R&D credits.

The Group has not recognised any deferred tax assets including 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 taxable income, taxable temporary differences and feasible tax planning strategies to utilise all the cumulative losses and it is probable that the deferred tax assets will not be realised in full.

#### 7. Loss per share (LPS)

The calculation of the basic and diluted LPS is based on the following data:

	6 Months ended	6 Months ended	Year ended
	30 Jun 2018	30 Jun 2017	31 Dec 2017
	Unaudited	Unaudited	Audited
	£'000	£'000	£'000
Loss:			
Loss for the period	(4,418)	(7,723)	(12,883)
Number of shares: Weighted average number of ordinary shares for the purpose of basic LPS Effect of dilutive potential ordinary shares: - share options	<b>78,205,609</b> -	78,120,802 -	78,141,096
- warrants	-	-	
Weighted average number of ordinary shares for the purpose of diluted LPS	78,205,609	78,120,802	78,141,096

In the six months ended 30 June 2018 and in the comparative periods presented, 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.

# Notes to the Condensed Consolidated Interim Financial Statements

#### 8. Investment in associates and joint ventures

At 30 June 2018, the Group held investments in one associate, PrEP Biopharm Limited, and one joint venture, Imutex Limited. A reconciliation of the carrying value of the Group's investments in joint ventures and associates is as follows:

	2018	2017
	£'000	£'000
At 1 January	12,553	14,150
Loss after tax recognised in the consolidated		
statement of comprehensive income	(362)	(606)
Other comprehensive income recognised in the		
consolidated statement of comprehensive income	47	(22)
At 30 June	12,238	13,522
		2017
		£'000
At 1 January		14,150
Loss after tax recognised in the consolidated		

	£′000
At 1 January	14,150
Loss after tax recognised in the consolidated	
statement of comprehensive income	(1,613)
Other comprehensive income recognised in the	
consolidated statement of comprehensive income	16
At 31 December	12,553

#### **PrEP Biopharm Limited**

hVIVO management has concluded that despite holding 62.6% of PrEP Biopharm Limited equity and having significant influence, the terms of the Investment and Shareholders' Agreement means that it does not have the power to direct the relevant activities of PrEP Biopharm Limited.

Accordingly, hVIVO's investment in PrEP Biopharm Limited has been accounted for as an investment in an associate.

#### **Imutex Limited**

hVIVO holds 49.0% of the equity of Imutex Limited and, under the terms of the Joint Venture Agreement, appoints two of the current four Directors. hVIVO management have concluded that the relevant activities of Imutex Limited are jointly controlled by the investors and therefore it is appropriate for hVIVO to equity account for the investment as a joint venture with joint control.

# Notes to the Condensed Consolidated Interim Financial Statements

#### 9. Trade and other receivables

	30 Jun 2018	30 Jun 2017	31 Dec 2017
	Unaudited	Unaudited	Audited
	£'000	£'000	£'000
Trade receivables	764	1,163	981
VAT recoverable	113	43	-
Other receivables	479	421	428
Prepayments	749	1,416	362
	2,105	3,043	1,771

£100,000 of other receivables was received in full post period end.

#### 10. Contract assets

	30 Jun 2018	30 Jun 2017	31 Dec 2017
	Unaudited	Unaudited	Audited
	£'000	£'000	£'000
Contract assets	13	17	417

## 11. Trade and other payables

	30 Jun 2018	30 Jun 2017	31 Dec 2017
	Unaudited	Unaudited	Audited
	£'000	£'000	£'000
Trade payables	1,123	1,605	1,103
Other taxes and social security	279	278	296
VAT payable	-	-	7
Other payables	44	79	446
Foreign current tax payable	8	14	-
Accruals	939	1,065	1,513
	2,393	3,041	3,365

#### 12. Contract liabilities

	30 Jun 2018	30 Jun 2017	31 Dec 2017
	Unaudited	Unaudited	Audited
	£′000	£'000	£'000
Contract liabilities	2,213	1,298	5,846

# 13. Post balance sheet events

Subsequent to the end of the financial period the Company announced it will cease its research & discovery activities and recently commenced a redundancy consultation process with affected employees. This will result in the closure of the scientific research facility in Welwyn, UK and the rationalising of operations into the Company's main site in London.

**hVIVO plc**Notes to the Condensed Consolidated Interim Financial Statements

# 14. Net cash used in operations

	6 months ended 30 Jun 2018 Unaudited £'000	6 months ended 30 Jun 2017 Unaudited £'000	Year Ended 31 Dec 2017 Audited £'000
Cash flow from operating activities			
Loss before taxation	(5,340)	(9,116)	(14,817)
Adjustments for:			
Share of loss of associates and joint ventures	362	606	1,613
Depreciation of property, plant and equipment	180	655	1,068
Amortisation of intangible assets	190	158	414
Share-based payments	255	48	144
Payment of Non-Executive Director fees by issue of	22	40	77
shares	22	40	//
Finance costs	27	27	54
Finance income	(30)	(42)	(71)
Gain on foreign exchange	-	(3)	-
R&D Expenditure Credit included in other income	(132)	(40)	(90)
Decrease in provisions	(672)	(206)	(851)
Changes in working capital:			
Decrease in inventories	189	8	244
Decrease in trade and other receivables, contract	70	633	1 507
assets and prepayments	70	033	1,507
(Decrease)/increase in trade and other payables	(4,591)	(2,818)	1,711
and contract liabilities	(4,331)	(2,010)	1,711
Cash used in operations	(9,470)	(10,050)	(8,997)
Finance costs	(27)	(27)	(54)
Income tax refund	-	-	4,000
Foreign tax paid	(17)	(15)	(14)
Net cash used in operating activities	(9,514)	(10,092)	(5,065)

Cash and cash equivalents includes short term deposits of £5.02 million (H1'17: £nil; 2017: £5 million).

# Independent Review Report of the Condensed Consolidated Interim Financial Statements of hVIVO plc

#### Introduction

We have been engaged by the Company to review the Condensed Consolidated Interim Financial Statements in the half-yearly financial report for the 6 months ended 30 June 2018 which comprises the Condensed Consolidated Statement of Comprehensive Income, the Condensed Consolidated Statement of Financial Position, the Condensed Consolidated Statement of Changes in Equity, the Condensed Consolidated Statement of Cash Flows and explanatory notes 1 to 14. We have read the other information contained in the half yearly financial report and considered whether it contains any apparent misstatements or material inconsistencies with the information in the Condensed Consolidated Interim Financial Statements.

This report is made solely to the Company in accordance with guidance contained in International Standard on Review Engagements 2410 (UK and Ireland) "Review of Interim Financial Information Performed by the Independent Auditor of the Entity" issued by the Auditing Practices Board. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the Company, for our work, for this report, or for the conclusions we have formed.

#### **Directors' Responsibilities**

The half-yearly financial report is the responsibility of, and has been approved by, the directors. The directors are responsible for preparing the half-yearly financial report in accordance with International Accounting Standard 34, "Interim Financial Reporting," as adopted by the European Union.

As disclosed in note 1, the annual financial statements of the Company are prepared in accordance with IFRSs as adopted by the European Union. The Condensed Consolidated Interim Financial Statements included in this half-yearly financial report has been prepared in accordance with International Accounting Standard 34, "Interim Financial Reporting," as adopted by the European Union.

#### **Our Responsibility**

Our responsibility is to express to the Company a conclusion on the Condensed Consolidated Interim Financial Statements in the half-yearly financial report based on our review.

#### Scope of Review

We conducted our review in accordance with International Standard on Review Engagements (UK and Ireland) 2410, "Review of Interim Financial Information Performed by the Independent Auditor of the Entity" issued by the Auditing Practices Board for use in the United Kingdom. A review of interim financial information consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing (UK) and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

#### Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the Condensed Consolidated Interim Financial Statements in the half-yearly financial report for the 6 months ended 30 June 2018 is not prepared, in all material respects, in accordance with International Accounting Standard 34 as adopted by the European Union.

Ernst & Young LLP Reading, United Kingdom 19 September 2018

Ernst & Young LLT