



The human solution

Annual Report and Financial Statements 2015

Vision: revolutionise healthcare by putting humans at the heart of disease modelling.

Mission: overcome unmet medical need barriers by providing human models of disease which bridge the translation gap from animal to man, and which can illuminate the molecular and cellular causes of disease.

Better treatments, faster

The demand for new treatments in the drive towards a healthier world is a pressing one. There is a real need to understand better the true causes of debilitating and life threatening conditions and identify the best way to alleviate or cure them.

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Our highlights

During the past two years we have made rapid progress in advancing the hVIVO platform to start realising its massive potential and value, culminating in our 2015 investment in PrEP Biopharm with its flagship product PrEP-001.

Financial highlights



- Revenue of £7.7 million (2014: £18.5 million) is consistent with expectations communicated in November 2015, due to the slower re-build of client engagements and PrEP Biopharm licence arrangements deferring revenue recognition to completion in 2016
- Gross profit of £2.5 million and gross profit margin of 31.8% (2014: gross profit £5.5 million and gross profit margin 29.6%)
- Research and development expense was £10.2 million (2014: £10.7 million) reflecting ongoing commitment to discovery research and product validation capabilities and programmes
- Administrative expenses were £13.7 million (2014: £17.7 million) with the reduction primarily due to efficiently managing our resources
- Completed successful fundraising during the year raising £20.5 million before expenses (2014: £33.6 million before expenses)
- Strong financial position with short-term deposits, cash and cash equivalents of £51.2 million at 31 December 2015 (2014: £50.8 million)

Operational highlights



- Made a significant equity investment in PrEP Biopharm Limited with its flagship prophylactic compound PrEP-001, a compound in which the hVIVO platform played a fundamental role in its progression to-date
- Progressed PrEP-001 Phase II clinical studies in flu, asthma and durability with first readouts expected by end of H1 2016
- Produced first pathomics map of host response in flu
- Completed severe flu drug target qualification, enabling hVIVO's progression from pre-discovery to productisation in less than a year
- Launched asthma model using our calibration process, establishing a new gold standard and beginning our first product validation study for asthma in 2016, less than a year after initiation
- Obtained ethics approval for landmark study to collect human samples, stratify asthma, and begin work to identify patterns from human sample data, connecting digital and biological data to define disease "algorithms" for asthma disease management
- Expanded our services and licensing options to explore collaborations and equity investments as we partner with pharmaceutical and biotechnology companies to accelerate drug development

Case studies

Case study:
severe flu
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Case study:
asthma model launch
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Chief Executive Officer's statement



hVIVO has shown the incredible value that is inherent in using human-derived data in both the pre-discovery phase and in early-stage clinical trials.

Kym Denny

Chief Executive Officer

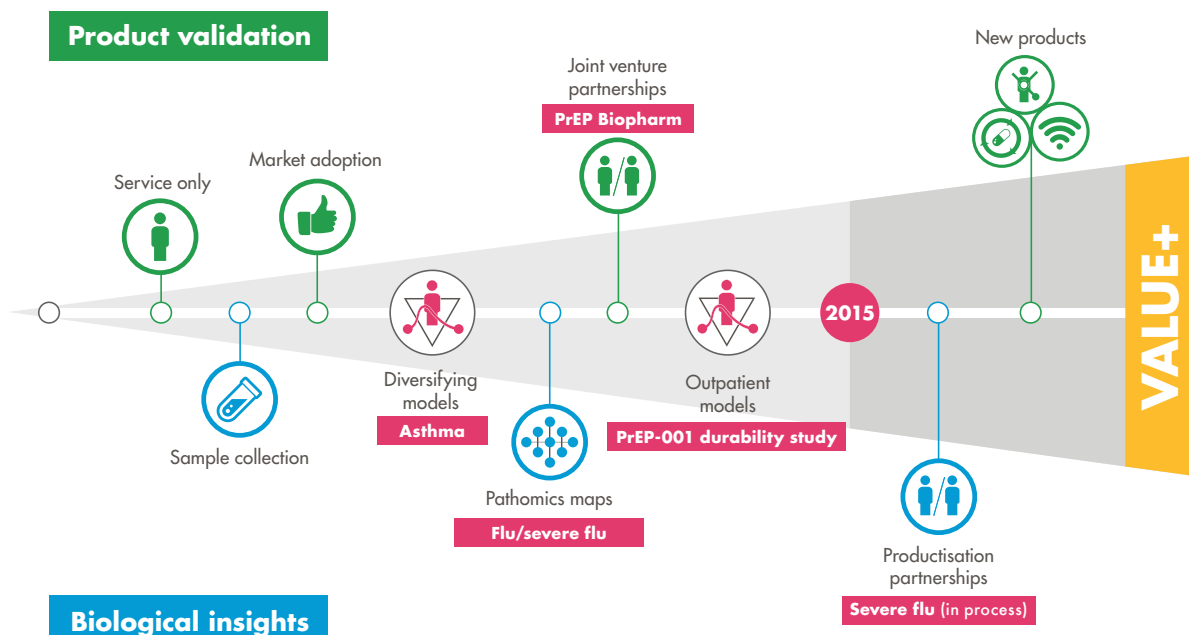
2015 was a year of achievement and evolution for hVIVO. hVIVO acquired a significant equity stake in PrEP Biopharm Limited ("PrEP Biopharm") a new UK biotech company with its prophylactic compound PrEP-001, a compound where hVIVO's platform has been a fundamental contributor to its success to date. This allows hVIVO, for the first time, to participate in the upside value generated by the product insights our platform provides. We are leveraging the platform's speed of conduct for early phase research and application of its biological insights to simplify later phase studies - further enhancing PrEP-001's potential going forward.

2015 also saw another significant first for the company, with hVIVO delivering the first map describing the human response to flu. Even more noteworthy than gaining this proprietary biological insight was the speed at which we were able to turn our insight into action: we progressed to drug target qualification in less than one year, which represents a staggering 90% reduction on traditional pre-discovery timelines. Such timeline compression was made possible due to the very heart of our organisation: the profound 'disease in motion' samples that our platform generates.

Buoyed by the results of our flagship 'pathomics' map in flu, in 2015 we expanded our capabilities into respiratory diseases, starting with asthma. We have since commenced work on a groundbreaking sample collection initiative that will enable asthma patient stratification and benchmarking of targeted therapies for the first time. In 2015 we began building hVIVO's commercial infrastructure to fuel our innovative product efforts and support new, more collaborative client relationships. The year finished with a successful capital raise in November 2015 to support our building momentum in asthma, flu and PrEP-001 product development. Thus, 2015 was a corner-turning year for hVIVO, one in which we begin to take the guesswork out of biology by illuminating the right targets and biomarkers for more streamlined and cost-effective drug development, positioning us to participate in the upside our insight creates as an equity stakeholder.

This human-based approach has not only fuelled our research, it has enabled our platform as a benchmarking tool. During the past five years, data from the hVIVO platform has underpinned the progress of a number of our clients' drugs. Several of these products were the foundation for nearly \$2 billion in M&A transactions in the infectious disease sector. The success of three of these drugs resulted in the sale of entire companies, the largest of which was Janssen's acquisition of Alios. Indeed, Johnson & Johnson said publicly that two of hVIVO's client drugs, AL 8176 for respiratory syncytial virus (RSV) and JNJ-872 (VX-787) for influenza A, were "expected to drive growth in the next several years."

PrEP Biopharm transaction marks a new era of value creation for hVIVO



Realising the value of hVIVO's platform

In 2015, hVIVO made evolutionary progress towards realising the platform's value contribution to product success. We delivered the first map of host response in flu and rapidly progressed to productisation in less than a year's time. We expanded into respiratory and launched our first model, asthma. The year culminated in the equity investment in PrEP Biopharm with its compound PrEP-001 after a successful proof of concept within the hVIVO platform.

Our human-based approach has fuelled this success and established the hVIVO platform as a benchmarking tool, supporting nearly \$2 billion in M&A transactions over the last five years alone.

This year's PrEP Biopharm transaction marks the beginning of a new era of value creation for hVIVO. It is the first step towards fully leveraging the power of the platform to revolutionise drug and diagnostic development, providing a launchpad for future products in 2016 and beyond.

hVIVO platform in motion: PrEP-001

Two years ago, hVIVO conducted a proof of concept study for Janssen using the hVIVO platform. This study demonstrated that Janssen's compound (now renamed PrEP-001) achieved a threefold reduction in clinical illness and an eightfold reduction in common cold symptoms compared with a placebo. With these promising results, we saw tremendous commercial potential for PrEP-001. Working with the other main PrEP Biopharm investors, which include Johnson & Johnson Innovation-JJDC Inc and the founders of PrEP Biopharm, we executed the PrEP Biopharm transaction in short order, completing it on 1 November 2015. From summer 2015, hVIVO commenced the complex clinical trial start up activities in order to target positioning of PrEP-001 for field Phase IIb by the end of 2016; and just over a year from completion of the PrEP Biopharm transaction.

Our investment in PrEP Biopharm with its compound PrEP-001 gives hVIVO the powerful opportunity to showcase the value of the hVIVO platform in predicting a drug's future success in field studies. In the laboratory-like setting of our platform during 2015 and 2016, we are answering as many human-specific questions as we can to best position PrEP-001 to succeed in its field-based trials. These questions form the *raison d'être* behind the three PrEP-001 clinical studies we are currently conducting:

- Does PrEP-001 also work in flu?
- How long does the drug's effect last?
- Does it prevent colds in asthmatics, thereby reducing their chances of asthma exacerbation?

It seems obvious that one would want to answer these questions early in product development, but the nature of the patient populations and the lack of understanding of our body's response to viruses makes the development pathway complex and costly, and such questions historically could only be answered in large field based studies. By answering these questions in the hVIVO platform, the eventual field work can be fine-tuned, reducing the risk of aiming at the wrong patient population or indication in expensive field studies.

Chief Executive Officer's statement continued

A new approach:

One of the key hurdles in today's drug development paradigm is the difficulty of mapping the underlying mechanics of disease: to identify root causes and define the levers that affect development. This critical step typically takes more than ten years. But with our innovative human-based approach, we will have completed the pre-discovery phase in flu in under one year's time, reducing the duration by 90%.

Expanding our reach:

Two different landmark studies conducted by hVIVO for RSV therapies were published in the New England Journal of Medicine. Given this success, we are using the same approach to develop new models for respiratory diseases, starting with asthma.

Defining severe flu levers and dials

One of the key hurdles in today's drug development paradigm is the difficulty of mapping the underlying mechanics of disease: to identify root causes and define the levers that affect development. This critical step typically takes more than ten years. But with our innovative human-based approach, we will have completed the pre-discovery phase in flu in under one year's time – reducing the duration by 90%.

In analysing the samples acquired during our studies, we have the unique opportunity not only to observe disease in motion but also to monitor and check the wiring in the body's circuitry, or "pathomics" – a term we coined to describe this approach. Pathomics is a combination of "pathways," or signalling networks, and "omics," the collective technologies used to explore the various types of molecules that make up the cells of an organism. Pathomics involves data mining and analysis, "disease-in-motion" sample acquisition, product validation and disease research. We use these techniques to elucidate and define the most influential signalling human pathways that underpin the host response. We are in essence, providing a biological global positioning system (GPS) to define the key components that are directly involved in human disease, including drug targets and biomarkers.

In early 2015 we completed the first ever pathomics map of the human response to flu infection and then built out the critical pathways for severe flu. Initially, we charted biomarkers in those patients who contracted flu and returned to health after a few days. From there, we studied samples from patients with severe flu to complete the seminal task of identifying the biological "tipping point" when flu becomes severe. Knowing the tipping point is crucial, as it enables us to rationally select drug targets and essential predictive biomarkers. I am immensely pleased and proud to say that we have very recently completed our qualification process to determine drug targets, pathway biomarkers and disease activity biomarkers. This is a pivotal moment for us, as we are now positioned to advance our discoveries into candidate status in 2016, with products that could include drugs to treat flu, biomarker tests to guide clinical product development, and predictive tests to identify flu susceptibility and patients at risk of severe flu.

Delivering the next gold standard: Asthma

When hVIVO began working with respiratory syncytial virus (RSV), it was not a well-understood disease. We defined and calibrated a disease model that has now become the gold standard. Two different landmark studies conducted by hVIVO with Allos and Gilead for RSV therapies were both published in the highly respected New England Journal of Medicine. Given this success, we are using the same approach to develop new models for respiratory diseases, starting with asthma.

Asthma is a complex disease that affects more than 300 million people worldwide and, like flu and colds, asthma has no effective cure. It is comprised of subgroups with differing characteristics and potentially different therapeutic demands. This year, hVIVO achieved a significant milestone with the official release of our human model of viral-induced asthma exacerbation.

As we did with RSV, we first ran initial “calibration” studies to develop the model’s product specifications (i.e. endpoints, recruitment rates, trial design) to ready the model for release. This coming year, we will be conducting ground-breaking research in moderate to severe asthma patients, collecting and analysing samples to define asthma patient subtypes and identify disease mechanisms. These results will provide hVIVO, for the first time, the ability to stratify patients and benchmark targeted therapies – eliminating the mass numbers and uncertainties inherent in today’s asthma trials. In addition, our ability to collect and analyse samples to identify patterns of association offers a compelling opportunity to connect biology and digital data to design powerful disease algorithms, and work is ongoing in 2016 in this area.

November 2015 Fundraise

Our aspirations to advance our key programmes for PrEP-001, asthma and severe flu were highlighted during our November 2015 fundraise. Throughout the process we experienced tremendous support and excitement and were delighted to raise £20.5 million from existing shareholders. These funds will be principally used by hVIVO to progress PrEP-001 to Phase IIb field studies, commence the stratification of asthma and advance the flu pathomics outputs into product candidates.

The PrEP Biopharm transaction signals that the hVIVO platform has successfully evolved to a comprehensive drug discovery and development platform with both services and product development engine capabilities, enabling hVIVO to exploit the power and value generation of its human disease models.

hVIVO strives to ‘get the biology right from the start’. We leverage our insight to produce the right drugs and to reduce the time, cost and complexity of clinical development itself. This approach enables hVIVO to turn biological verification on its head and position our platform early on in a product’s lifecycle, rather than waiting until the final human testing phase (Phase III) to confirm the right targets and biomarkers have been selected.

We have reached the next chapter in the evolution of the hVIVO platform, where we now seek to achieve a balance of client engagements (generating revenue, gross profit and contribution to cash flow) with investments such as PrEP Biopharm and our own internal R&D engagements, to maximise the utilisation of our resources, together with cost efficiency driving value creation for shareholders.

Commercial evolution

The commonality in our accomplishments in 2015 was the strengthening of the hVIVO platform and its state-of-the-art market position for revolutionising R&D. None of our foundation setting for the future would have been possible without the tremendous progress we have made in advancing our research methods and fine-tuning our results. hVIVO has shown – and continues to demonstrate – the incredible value that is inherent in using human-derived data in both the pre-discovery phase and in early-stage clinical trials.

Given our unique status as the only commercial provider of multiple human disease models, hVIVO is poised to explore potential collaborations and equity investments. We have made a strategic decision to partner with pharmaceutical and biotech companies and help them accelerate the drug discovery and commercialisation process. We can help clients with their drugs in flight with our service business, and then with our proprietary pathomics biological insights and knowledge. We are able to do this both with drugs that are currently in development and those that were previously shelved, in order to reposition them for new commercial opportunities. We can also help clients identify the drugs of the future. As such, we are continuing to expand our services and licensing options through collaborations and equity investments with select customers and products. Ultimately, we believe these collaborations will drive increased shareholder value.



Chief Executive Officer's statement continued

A pivotal moment

I am immensely pleased and proud to say that we have very recently completed our qualification process to determine drug targets, pathway biomarkers and disease activity biomarkers. This is a pivotal moment for us, as we are now positioned to advance our discoveries into candidate status in 2016, with products that could include drugs to treat flu, biomarker tests to guide clinical product development, and predictive tests to identify flu susceptibility and patients at risk for severe flu.

Corporate leadership

As hVIVO continues to grow and evolve, so does our corporate leadership at the Board level. I am pleased to announce that Mark Warne has joined the hVIVO Board as a Non-Executive Director on 19 April 2016. Mark brings a wealth of technology commercialisation experience to guide hVIVO into its next chapter of product development and value creation. He is Head of IP Group's Healthcare division which at the end of December 2015 had shareholdings in 31 companies valued at over £275 million. He also represents IP Group plc on the boards of a number of its portfolio companies, both quoted and private. Mark Warne has been at IP Group since 2008 and has extensive experience in building world-changing healthcare businesses as well as in managing transactions including portfolio company IPOs, financings and M&A.

As we welcome Mark onto the Board, two of our valued board members will be retiring by rotation at our Annual General Meeting and not seeking reappointment. While Dave Norwood, who was appointed Chairman of the Board in 2011 and served in that capacity until 2014, will be retiring at our May 2016 AGM as a Non-Executive Director, he will continue to support hVIVO as a strategic consultant. Dave has played a pivotal role in crafting the hVIVO vision and business strategy since 2011, along with providing stewardship as a Director. In his new role as a consultant to hVIVO, he will continue to support me and the Board in the development of our strategy and our investor relations, and I am delighted to continue to work with him in this capacity. Also retiring at our May AGM is Ali Fielding, who has served as Non-Executive Director of hVIVO since July 2014. Ali has been an inspiration to me for many years, with a wealth of experience building high performance companies, and I am deeply grateful for all her guidance and support in helping hVIVO navigate the complexities of evolving into a products-based organisation. I would like to thank both Dave and Ali for serving on the Board and for helping to steer hVIVO's evolution on our journey to revolutionise drug development by putting humans at the heart of discovery.

Outlook

During the past two years we have made rapid progress in advancing the hVIVO platform to start realising its massive potential and value, culminating in our investment in 2015 in PrEP Biopharm with its flagship product PrEP-001. This landmark achievement speaks to the strategic goals and capabilities of hVIVO: leveraging biological insights to create better treatments faster. As evidence of the value of this approach, we have already made enormous strides since we last visited our investors in November 2015: we have completed the qualification phase of our flu drug targets and biomarkers, completed the patient phase of the PrEP-001 flu study and started it for the other two PrEP-001 studies, and we have received ethics approval for our asthma sample collection protocol, which allows us to start collecting those tremendously valuable and insightful samples in 2016.

We achieved qualification of our severe flu pathway components more than nine years faster than the traditional pre-discovery process. We have defined, for the first time, severe flu disease process and pathways at a molecular level by comparing healthy and severe samples to benchmark significant pathophysiological changes in severe flu. We assembled an impressive data package informing what biomarkers and drugs we should develop for identifying and treating those at risk for severe flu, as well as indicating those patients who are recovering after receiving therapy. Given the symbiotic relationship of our biomarkers being used to support target qualification, we anticipate being able to develop multiple products from this programme. We also anticipate this extensive knowledge will help promote a smoother and faster regulatory approval process. We are excited to officially commence our commercialisation journey for these revolutionary discoveries, thanks to the strong and widespread support from our investors.

The PrEP-001 studies are quickly progressing, with our initial results expected in first half of 2016. We have successfully enrolled and completed the flu study and are in the data analysis process as I write. In addition we have kicked off the PrEP-001 'durability' (dose duration) and asthma studies and remain on track to position PrEP-001 for field Phase IIb studies by the end of 2016, with the durability study also being hVIVO's first ever outpatient study. Meeting this objective will condense the traditional drug development timeline of over two years to just over a single year.

In 2015, hVIVO sought shareholder endorsement to push forward with our efforts to transform asthma management by better understanding the biology, which culminated in our £20.5 million fundraise in November 2015. Since then, we have developed, submitted and received ethics approval on the landmark study that will allow us to collect samples to stratify asthma. Work will be ongoing in 2016 and 2017. In 2016 we commenced our first investigational drug product validation study using our asthma model, paramount to beginning the exciting journey and market adoption similar to RSV.

Our rapid evolution and game-changing accomplishments in the past year set the stage for a dynamic 2016 and beyond. Our pivotal achievements of 2015 build a solid foundation for the future and could not have been attained without the hard work of our entire team, our volunteers, and your continuing invaluable support as shareholders. Thank you.



Kym Denny

Chief Executive Officer

19 April 2016

Taking the guesswork out of biology

Embracing the hVIVO spirit of helping organisations develop better therapies faster.

The missing link hVIVO's human-centered approach

The hVIVO platform puts humans at the heart of disease modelling. Volunteers are recruited for research studies in which a viral challenge agent is administered to elicit a self-limiting infection, such as flu, or to trigger a disease episode or exacerbation, such as in asthma patients. The studies are conducted under tightly controlled, quarantine conditions with full medical supervision.

How does this differ from traditional field studies? In field-based studies, patients are only recruited when they become symptomatic and are monitored at intervals. Unlike these studies, hVIVO's approach offers...

- **Personal baseline:** the healthy or pre-challenge subject acts as an internal control by providing a pre-disease baseline
- **Simplified correlation:** the laboratory-like conditions mean the presentation of symptoms against timeline together with cellular and molecular changes in response to the challenge agent can be tightly correlated
- **Disease movie-reel:** multiple, high quality samples can be taken from a range of body compartments throughout the course of the disease, or disease episode to provide a longitudinal 4D movie-reel view of the host response



hVIVO's fundamental premise is that we can accelerate drug and diagnostic development. Why are we so confident about this, and why is it so necessary?

Today much of the foundational disease biology research for drugs is done by the academic world. This pre-discovery work often takes ten to twenty years to be completed. Even with all of this work, there still remain many gaps in the understanding of the disease process overall, adding to the already long timelines companies face in bringing a drug to market. To overcome these gaps, the industry has become very good at developing drugs, at discovering the therapy "key" that opens a disease "lock."

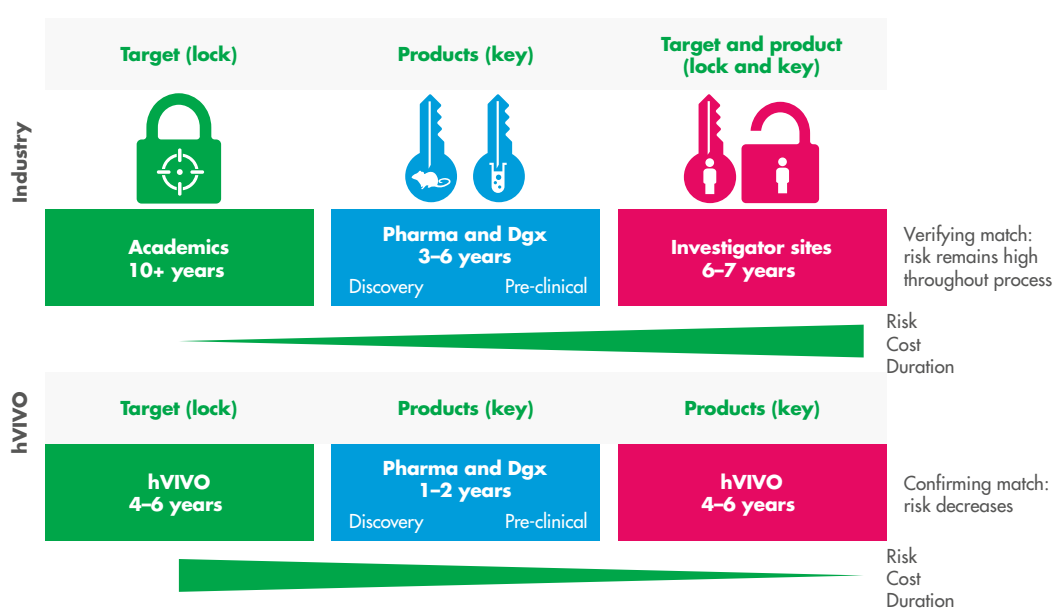
When companies proceed through the clinical trial process, they raise a compound against the lock they believe fits their key, primarily based on animal and pre-clinical derived indicators. The burden during the human-based trials process doubles – verifying that the drug works and confirming assumptions regarding the human disease biology itself. This inflates the number of subjects or patients required to go through the clinical trial process, drawing out the development timeline and dramatically increasing costs. Currently, only about 8% of new molecular entities make it all the way through clinical trials. The estimated cost of delivering a drug is more than \$2 billion, up from \$800 million just thirteen years ago. That results in high consumer health care costs.

At hVIVO, we pursue an alternative approach. Our human-based models and pathomics analysis enable us to track and identify disease targets or "locks" directly in people. Using these locks, we can help identify drugs or "keys" with hidden

potential by identifying, repurposing and reprofiling existing keys that have been shelved, as well as help find appropriate disease locks for new drug keys. Our work in understanding the biology will dramatically change the risk profile of a drug working or failing. Thus, our opportunity is twofold: to provide the right lock for the drug-key equation and to provide the information via biology points throughout the clinical trial process to make it less complicated. One example of reducing the complexity of clinical trials is our severe flu programme, where we are qualifying new pathways that are involved in flu. When this work is complete, we will have defined biomarkers that identify patients who are developing severe flu and will also indicate those patients who are recovering after receiving therapy.

Our disruptive platform is addressing the entire drug development problem. The missing link we provide is the "h" in hVIVO – humans. Unlike other pre-clinical studies, our data are based on human samples, which means they share the same biology as future recipients of the resulting drug therapy. By putting a commercial engine behind the biology identification problem, we are rationally selecting drug targets based on our understanding of the disease biology and leveraging hVIVO's biological insight to simplify and streamline the clinical trial process. In just over a year, we have not only identified the first map of the host response for flu, we have identified potential biomarkers and candidate drug targets for treating severe flu, reducing this step from more than ten years to just one year. And we have just begun with this one, and our first disease indication: all because we are taking the guesswork out of biology.

Matching lock and key



Matching lock and key

Due to gaps in the understanding of disease biology, the industry tries to verify product (lock) and target (key) at the same time, which bloats studies and increases costs. hVIVO leverages human models and pathomics to identify these locks in people and then uses these locks to identify keys – dramatically reducing risks, timelines, and costs.

Presenting: **PrEP Biopharm**

hVIVO's recent investment in the newly formed biotech company PrEP Biopharm Limited ("Prep Biopharm") with its flagship product PrEP-001 represent a transformational moment in our growth and development.

By the numbers

In the US alone, upper respiratory viral infections (URVIs) put a high burden on today's society

\$27 billion

in direct costs annually (US only)

189 million

missed school days per year (US)

200 million

missed work days

40 million

people at risk for life-threatening diseases, such as asthma, chronic obstructive pulmonary disease (COPD) and congestive heart failure



PrEP-001 provides the opportunity to see the hVIVO platform in action in the debilitating, yet unresolved area of upper respiratory viral infections.

With each person getting one to three cold and flu infections or URVI each year, totalling five billion and ten billion each year worldwide, there is a huge critical unmet medical need.

Average effectiveness for flu vaccines during the past ten years:
10% to 60%

Window for administering current flu therapies to be effective:
two days

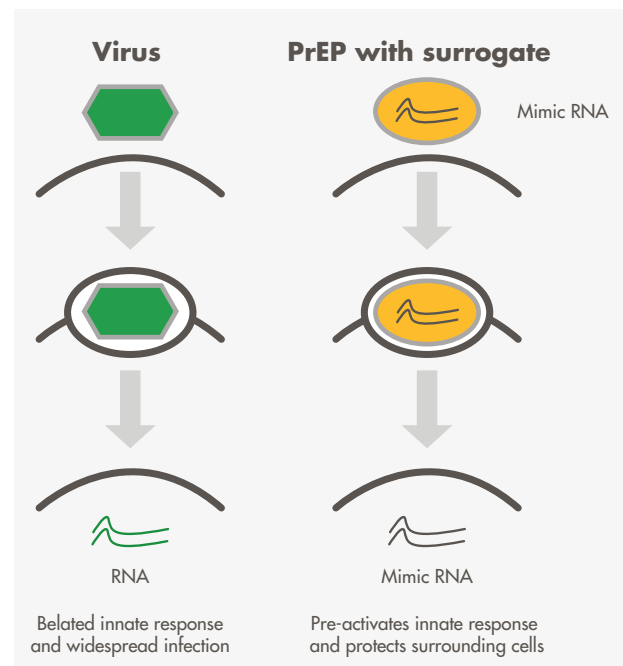
In spite of these numbers, there is little relief today from these diseases – there is no cure for the common cold, and current flu vaccines and treatments have significant limitations.

With initial proof of concept data in hand, PrEP Biopharm is aiming squarely at this unmet medical need. PrEP-001 is a nasally administered, broad-spectrum agent that leverages the innate immune system to prevent upper respiratory tract viral infections (colds and flus). This novel prophylactic nose spray delivers a benign surrogate for a respiratory virus into the nose which tricks the nasal lining cells into thinking they are being invaded by a real virus, which in turn activates the local innate immune defense system. In 2013, PrEP-001 demonstrated promising results in hVIVO's human rhinovirus (HRV) challenge model, reducing common cold symptoms by 8 fold compared with placebo in double-blind studies. New studies are underway in 2016 to verify performance against other respiratory viral infections such as flu.

How does it work?

During a typical upper respiratory infection, the virus enters into the nasal epithelium and replicates rapidly, spreading throughout the upper respiratory system in 24 to 72 hours. When PrEP-001 is administered, the nose responds to the inert particles (mimic RNA) as if they were viruses, activating the receptors that release interferon and triggering the innate immune response in the surrounding cells. This host response pre-arms the innate immune system so that when an actual virus arrives, it cannot replicate efficiently giving the adaptive immune system a chance to stop the virus before it can spread and infect the rest of the airway. PrEP-001 in effect creates a protective layer of nasal lining cells, preventing the viral infection.

The ultimate goal of such a prophylaxis would be to try to help a large number of patients who suffer substantial morbidity and mortality as a result of URVIs.



Case study

Infectious disease: severe flu

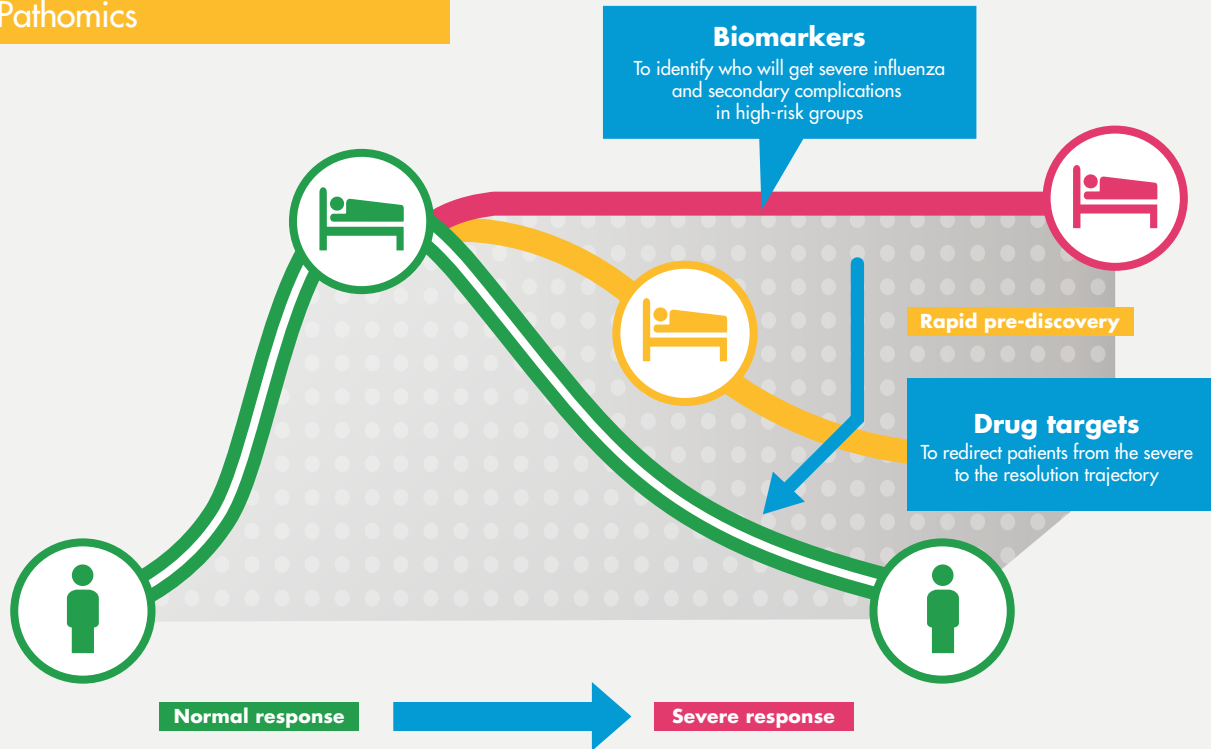
**Biomarkers****Drug development jet packs**

- Biomarkers can have a dramatic impact on drug development speed to market and costs
- Establishing disease process biomarkers early in drug development studies with the hVIVO platform could translate into 15% to 20% higher transition success rates at each Phase I, II and III trial for a typical influenza drug
- Higher success rates could result in savings of between \$100 million and \$360 million, on average, per drug
- Establishing biomarkers earlier in the trial process also could reduce the size and length of studies, de-risking the process and reducing the costs even more

Human-derived samples provide windows into the human disease process. Putting these windows or snapshots together in sequence over time and at different sites provides a unique 4D movie-reel of the human disease process – where pathways, targets and trigger sequence become clear. The insights gained and host response (pathomics) map generated from this reel then become a powerful blueprint for jump-starting future product development. Our rapid progress on flu and severe flu illustrates the speed possible using this approach: we have accomplished in one year what typically has taken more than ten years to achieve in traditional pre-discovery programmes.

hVIVO began our pathomics flu sample collection protocol in late 2014. We then set our sights on mining our platform for biological insights into the flu disease process. Simultaneously, we developed the analysis methodology for the wider pathomics discovery approach. We also built out our commercial infrastructure to safeguard our growing list of intellectual property and emerging proprietary know-how. From there, we evolved our strategy to develop two product types: hVIVO-enhanced products (drug development tools and drugs that are repurposed, repositioned and rescued, DRPx) and those that are hVIVO-derived from the platform's insights (*de novo* compounds, digital health solutions, and clinical assessment tests).

Rapid flu pre-discovery Pathomics



In early 2015, we established the first ever pathomics map outlining key biological pathways involved in the host response to flu infection. We obtained samples from patients hospitalised with severe flu and have begun the exciting task of identifying the biological “tipping point” when flu becomes severe in order to rationally select drug targets and predictive biomarkers. Throughout this process we have been progressing from discovery to proof of concept, working to define the right product fit.

We have completed the qualification process to determine the drug targets, pathway biomarkers and disease activity biomarkers for identifying patients at risk of severe flu illness as well as indicating those patients who are recovering after receiving therapy.

Rapid flu pre-discovery

hVIVO has been able to reduce pre-discovery time by 90% using biological insights produced by the platform to build the first flu pathomics map and identify the biological tipping points for developing severe flu. In 2016, drug target and biomarker selection was completed and productisation has begun.

Case study

Respiratory: asthma model launch

**Asthma****In need of a cure**

Asthma is a complex disease with high unmet critical need. There is no diagnostic test and, like colds and flu, it still has no effective cure

- More than 300 million people worldwide suffer from asthma and 10-20% are refractory to existing treatment
- Asthma generates a large medical burden: \$14.7 billion is spent each year on asthma-related healthcare. Hospitalisations from severe exacerbation comprise more than one third of that cost
- Experts describe asthma as not one homogeneous disease but as consisting of different phenotypes, each with differing characteristics and potentially different therapeutic demands

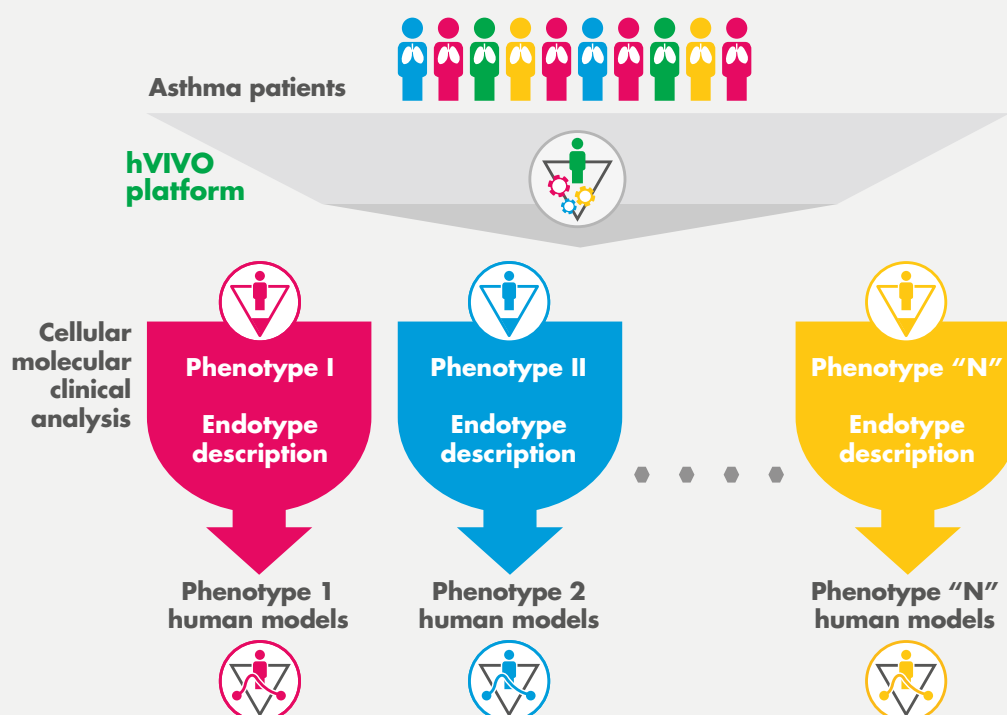
During the past year, hVIVO has advanced its commercial readiness, building on the foundation of its recent successes and expanding into new markets with the formal release of the hVIVO viral-induced asthma exacerbation model – our first commercial entry into respiratory diseases.

Following the successful development path of RSV, hVIVO achieved a significant milestone in 2015 with the official release of our human model of viral-induced asthma exacerbation, a powerful tool in benchmarking new therapies for asthma.

Asthma is a heterogeneous disease that affects millions and currently has no cure. More than 80% of asthma attacks or exacerbations are caused by viruses, primarily cold viruses. The hVIVO platform enables us to observe these asthma attacks or exacerbations “in motion” and within a controlled setting, allowing organisations to benchmark their therapies faster and earlier than traditional processes.

Additional studies involving moderate to severe asthma patients have received ethics approval and are underway in 2016. These studies will characterise asthma patient phenotypes and biomarkers associated with the host response. The results will enable the platform to classify asthma subtypes by molecular, clinical and cellular criteria for defining specific endotypes and stratifying asthma patients. Doing so could yield, for the first time, a way to differentiate among asthma patients. It also would create the biological insights necessary to select the right drug targets for each asthma subtype, allowing hVIVO to develop new drugs and to test existing assets for sub-type effectiveness. In time we also see the same approach being applied to new models such as COPD.

Asthma stratification approach



Because the hVIVO platform addresses two of the key pain points in our industry – reliable pre-discovery and fast and efficient clinical trials – we can add tremendous value in a collaborative fashion. We can conduct targeted, more informed clinical trials for better decision making, reinvigorate existing drug assets with reprofiling and repositioning, and support rational selection of future assets through hVIVO-derived targets and biomarkers.

To support our increasing commercial demands from new products and services for areas such as asthma and severe flu, we have expanded our sales force and based it in the US. This will enable us to have a more global reach, grow our marketing capabilities and support partnering opportunities. The goal of these investments is to broaden our customer activities and develop new platform-based products with existing and new pharmaceutical and biotechnology clients as we expand into new markets. We have implemented sales and marketing plans and have begun our first investigational drug product.

Asthma stratification

Upcoming asthma studies will enable hVIVO to characterise moderate to severe patients and define subgroups or endotypes, enabling the platform to stratify patients for the first time. The insights generated will enable hVIVO to select targets, identify drugs, and benchmark therapies effectiveness against asthma endotypes.

Market context

The hVIVO platform is beginning to take the guesswork out of biology, illuminating the right targets and biomarkers for more streamlined and cost-effective drug development.

The estimated cost
of delivering a drug is more than

\$2bn

Source:
Tufts Centre for Drug Development 2014.

Drug development is a long and expensive process, where success is often limited by the lack of understanding of the disease process itself. This results in the inability to match targets and drugs, like locks and keys, early in the process, leading to costly, bloated later-stage trials to address the uncertainties. The estimated cost of delivering a drug is more than \$2 billion, up from \$800 million just thirteen years ago. That is largely because of the lack of reliable pre-discovery and fast and efficient clinical trials. Poor information inflates the number of subjects or patients required to go through the clinical trial process, extending the development timeline and dramatically increasing costs. In fact, only about 8% of new molecular entities make it all the way through clinical trials, taking between ten and twenty years.

hVIVO's disruptive platform is addressing the entire drug development problem. The missing link we provide is the "h" in hVIVO – humans. Unlike other pre-clinical studies, our data are based on human samples, which means they share the same biology as future recipients of the resulting drug therapy. By putting a commercial engine behind the biology identification problem, we are rationally selecting drug targets based on our understanding of the disease biology and leveraging hVIVO's biological insight to simplify and streamline the clinical trial process – taking the guesswork out of biology.

During the past two years, we have made rapid progress in advancing the hVIVO platform to start realising its massive potential and value, culminating in our 2015 investment in PrEP Pharma with its flagship product PrEP-001. This landmark achievement speaks to the strategic goals and capabilities of hVIVO: leveraging biological insights to create better treatments faster. As evidence of the value of this approach, we have already made enormous strides since we last visited our investors in November 2015: we have completed the qualification phase of our flu drug targets and biomarkers, completed the patient phase of the PrEP flu study and started it for the other two PrEP studies, and we have received ethics approval for our asthma sample collection protocol, which allows us to start collecting those tremendously valuable and insightful samples in 2016.

Business model and strategy

Business model

Discover new biomarkers and drug targets to pave the way for the next generation of therapeutic and diagnostic products

Diversify into adjacent markets by developing the hVIVO platform into new disease areas

Partner with pharmaceutical companies through collaborations and equity investments

Use pathomics to expand our discovery R&D capabilities to understand the biological pathways involved in the human response to disease

Use service business to generate gross profit, enhance customer relationships and partially fund R&D

Objectives

- Expand the hVIVO platform into new diseases to illuminate molecular and cellular causes in areas of high unmet medical need

- Institute processes and structure to protect IP and support product commercialisation

- Expand sales pipeline through collaborative relationships with pharmaceutical industry

- Advance PrEP-001 in clinical trials

- Accelerate drug discovery and commercialisation through delivering high-quality product validation capabilities

Progress in year

- Launched asthma model using our calibration process, establishing a new gold standard and beginning our first product validation study for asthma in 2016, less than a year after initiation
- Obtained ethics approval for landmark study to collect human samples, stratify asthma, and begin work to identify patterns from human sample data, connecting digital and biological data to define disease "algorithms" for asthma disease management

- Produced first pathomics map of host response in flu

- Expanded our services and licensing options to explore collaborations and equity investments as we partner with pharmaceutical and biotechnology companies to accelerate drug development

- Made a significant equity investment in PrEP Biopharm Limited with its flagship prophylactic compound PrEP-001, a compound in which the hVIVO platform played a fundamental role in its progression to-date
- Progressed PrEP-001 Phase II clinical studies in flu, asthma and durability with first readouts expected by end of H1 2016

- Completed severe flu drug target qualification, enabling hVIVO's progression from pre-discovery to productisation in less than a year

See page 20 to 23 for associated risks

Financial review



During the past five years, hVIVO's platform has helped the forward progression of multiple drugs. Our human-centered approach enables clients to benchmark their therapies and remove biology guesswork, helping them reduce drug development time and costs.

Graham Yeatman

Chief Financial & Business Officer

This year saw a rapid evolution of hVIVO as we leveraged the hVIVO platform's novel biological insights in flu to reach target qualification in under a year, and launched our first human disease model in respiratory diseases for asthma. The Company's investment in PrEP Biopharm allowed hVIVO to obtain a significant stake in a new company developing a product that is well placed to transition into later phase trials in at-risk patient groups. During the past five years, hVIVO's platform has helped the forward progression of multiple drugs. Our human-centered approach enables clients to benchmark their therapies and remove biology guesswork, helping them reduce drug development time and costs.

The November 2015 fundraise provided shareholder support and allowed hVIVO to further utilise the skills, resources and expertise that it has developed over the last two years, to build out bioinformatics analysis and disease stratification capabilities as hVIVO works to identify novel biomarkers and drug targets in areas of high unmet medical need.

Financial KPIs	2015	2014
Revenue	£7.7m	£18.5m
Gross profit	£2.5m	£5.5m
Gross profit margin	31.8%	29.6%
Research and development expense	£10.2m	£10.7m
Administrative expense	£13.7m	£17.7m
Loss for the year	£(17.9)m	£(18.4)m
Short-term deposits, cash and cash equivalents	£51.2m	£50.8m

Revenue

Revenue for the year ended 31 December 2015 was £7.7 million (2014: £18.5 million) and is consistent with expectations communicated in November 2015, due to the slower re-build of client engagements and PrEP Biopharm licence arrangements deferring revenue recognition to completion in 2016.

Under the terms of the PrEP Biopharm transaction, PrEP Biopharm contracted with hVIVO Services Limited for the delivery of hVIVO owned intellectual property in flu and asthma under licencing arrangements and also to conduct a Phase II durability study for a total consideration of £10.0 million. hVIVO commenced its programme of work in September 2015 and the programme was well progressed by the 2015 year end. As a consequence of flu and asthma being under licence arrangements, the revenue and costs attributable to this work will be accounted for on a "completed" basis in 2016 rather than on a "work done" basis, as is currently the case for the revenue recognition of hVIVO's standard clinical trials agreements with clients. The programme of work is forecasted to complete during 2016 and revenue of £10.0 million recognised in full by the 2016 year end.

Research and development expense

The Group's research and development expenses totalled £10.2 million (2014: £10.7 million). This reflects hVIVO's continued investment in discovery research and product validation capabilities and in particular disease research (pathomics), data mining and analysis, sample acquisition and product validation processes.

Administrative expense

Administrative expenses were £13.7 million (2014: £17.7 million). The reduction is primarily due to managing the efficiency of our resources, restructuring our operations and implementing cost saving initiatives during the period. Administrative expense in 2015 included £1.0 million of leasehold provisions (2014: £3.7 million of leasehold provisions and impairments).

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 £3.7 million for the year ended 31 December 2015 (2014: £3.9 million).

Consolidated statement of financial position

As of 31 December 2015 total assets less liabilities amounted to £63.6 million (2014: £61.2 million) including short-term deposits of £37.0 million (2014: £28.0 million) and cash and cash equivalents of £14.2 million (2014: £22.8 million).

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

- acquisition of equity in PrEP Biopharm of £14.4 million which includes £0.4 million of transaction costs;
- recognition of a current intangible asset of £2.9 million relating to flu and asthma licence arrangements;
- increase in short-term deposits of £9.0 million;
- decrease in cash and cash equivalents of £8.6 million; and
- increase in current trade and other payables of £12.9 million, which includes £5.0 million relating to deferred consideration for the acquisition of PrEP Biopharm equity paid in January 2016.

Cash flow

The principal cash flows in the year were as follows:

Inflows

- net proceeds on issue of shares of £20.2 million (2014: £32.8 million); and
- finance income of £0.4 million (2014: £0.4 million).

Outflows

- cash outflow from operating activities of £9.8 million (2014: £16.6 million);
- purchase of property, plant and equipment of £0.9 million (2014: £1.4 million); and
- payment for equity investment in PrEP Biopharm of £9.4 million, inclusive of £0.4 million of transaction costs (deferred consideration of £5.0 million paid in January 2016).

Key performance indicators

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

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

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

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

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



Graham Yeatman

Chief Financial & Business Officer

19 April 2016

Principal risks and uncertainties

hVIVO continues to improve on and implement policies, procedures and standards of practice intended to identify, monitor and reduce risk.

Our risk management policies are regularly reviewed and look to take into account current market conditions, hVIVO activities and strategic direction. There will be known and unknown risks which could potentially impact on the future performance of hVIVO which are not cited within this report. Risks that present a potential material impact are identified and governed in accordance to our risk management policies.




Governance structure of risk management






Risks are defined and referenced to magnitude of impact and likelihood of occurrence within the hVIVO corporate risk register and are reported in line with the adjacent escalation and risk management process. All employees of hVIVO carry a role and responsibilities in risk monitoring, reporting and management. Regular reviews are taken to ensure compliance.




A summary of the principal risks and uncertainties which pose a material risk to the performance of hVIVO are sectioned in three categories of risk as detailed in the table adjacent.

Risk category	Description
STRATEGIC	Strategic risks which could have an internal or external influence and would impact on hVIVO's ability to perform or advance from today's position.
OPERATIONAL	Operational risks which may impact on hVIVO's ability to deliver on its objectives – resulting in an internal impact.
FINANCIAL	Financial risks which may impact on the sustainability or liquidity of the Company – affected by internal or external risks.

Principal risk	Category	Mitigation
<p>Regulatory, quality and ethics framework</p> <p>Failure to comply with legal, regulatory and ethical frameworks and/or regulations covering health and safety, Good Clinical Practice ("GCP") MHRA, FDA and all other appropriate bodies resulting in:</p> <ul style="list-style-type: none"> core business being curtailed pending investigations for a period of time; inability to deliver studies or closure; data and sample integrity and/or subject safety being affected; and potential legal action. 		<ul style="list-style-type: none"> hVIVO ensures appropriate steps are taken and formalised training is provided under the QMS ("Quality Management System") internal audit schedule in our monitoring and management to ensure adherence with all safety policy and regulations including but not exclusive to Global RMP and FDA risk evaluation and mitigation strategies. hVIVO also complies with the EU Data Protection Directive. hVIVO operates a single QMS governed by senior quality and regulatory professionals. Our Senior Medical Director & Responsible Officer has delegated authority from NHS England (and ultimately the General Medical Council) to ensure the systematic assessment of doctors operating at hVIVO, and to validate that they are safe and competent to operate on a continuing basis in their medical capacity. Study participants are fully informed of the possible risks and are free to choose whether or not to participate in a study. The Quality Governance Group provide governance over Standard Operating Procedures and Corrective Action/Preventive Action processes which are regularly reviewed with Internal audit teams. For target qualification process, hVIVO is devising methods by using human-based data.
<p>Intellectual property and patent protection</p> <p>Failure to secure and protect intellectual property ("IP") due to number and complexity of patents in sector could place freedom to operate restrictions.</p> <p>New laws on clinical trial patent exemptions and scope in US, UK and Europe could compromise the enforcement of patents within the clinical trial industry.</p> <p>hVIVO could be challenged and may have to respond to objections to new patent applications from the European Patent Office or third parties opposing patent grants.</p>		<ul style="list-style-type: none"> hVIVO uses all aspects of intellectual property to protect its model: patents, trademarks, copyrights and trade secret. hVIVO engages and utilises internal and external patent experts to define intellectual property protection strategies and responses to objections and/or patent opposition. Continuous mapping of the IP landscape to identify threats and opportunities and avoid infringements. Integrated and concerted workflows to execute the R&D, IP, product development and commercial strategies.
<p>Competition</p> <p>The life sciences industry is subject to rapid technological change which could affect hVIVO's product viability.</p> <p>The emergence of competition could impact our market potential and/or lead to pricing pressures and demand shortfall. Failure to compete could impact on hVIVO's future revenues and profitability.</p>		<ul style="list-style-type: none"> hVIVO continues to monitor competitor developments and pricing positions to protect acquired assets and new product development. hVIVO is investing in translational medicine, collaborations and equity investments, and other partnerships to promote new product development. hVIVO's human-based approach involves collecting and analysing human-based samples during studies to research and understand disease biology, enabling it to evolve its platform, support new product development and maintain its significant advantage over existing and potential competition, by increasing its wealth of know-how, proprietary information, virus library, and experience built over many years of successful operation of the human disease model with its own viruses. hVIVO's human-based approach has enabled it to diversify its product portfolio to include product validation services (including asset development) and discovery research for respiratory and infectious diseases (new product development), helping to buffer the Company from technological changes in one area.

Principal risks and uncertainties continued

Principal risk	Category	Mitigation
<p>Collaboration</p> <p>Failure to identify and secure appropriate investment opportunities and/or poor value assessment and integration could negatively impact our ability to build and realise the benefits of collaborations.</p> <p>Failure to deliver on obligations on either side of partnerships could also impact on our ability to develop, produce and/or commercialise our products which would adversely impact our cash flow and strategic objectives.</p>		<ul style="list-style-type: none"> • hVIVO invests in attracting appropriate collaborative partnerships, joint ventures and licensing agreements which are core to our business strategy. • hVIVO is selective and applies extensive due diligence, including support from external experts to ensure that wider due diligence team has the necessary breadth and depth of knowledge and experience. • Successful integration of the recent ventures has created a blueprint for future partnerships and collaborations. • Internal controls reduce the risk, while our delivery builds our reputation and allows for better attraction and retention capability.
<p>Research, discovery and development</p> <p>Failure to realise hVIVO's scientific research and product development plans would impede on our strategic delivery and adversely impact on financial performance.</p> <p>Failure to achieve regulatory approval could cause delays and additional costs.</p> <p>Failure to focus research on commercially important areas would impact R&D value.</p>		<ul style="list-style-type: none"> • hVIVO accesses guidance from regulatory experts to refine expectations for future study requirements. • hVIVO invests in scientific discovery for future revenue growth and monitors R&D performance. • Integration of risk appetite with strategic planning governs R&D orientation, requirements, spend and targets. This approach ensures investment keeps pace with R&D programme milestones to appropriately balance risk management with vision and entrepreneurship. • Recruiting in both R&D and Translational Medicine to enhance our knowledge and expertise in new therapeutic areas.
<p>Applying the human disease model in new therapeutic areas</p> <p>There is a risk that new applications of the human disease model are not adopted by the industry.</p> <p>Failure to ensure that infectivity rates are in line with commercial viability and delivery of a study could impact our reputation and revenue.</p>		<ul style="list-style-type: none"> • hVIVO is pioneering the human disease model so is in a unique position to discuss and help define regulatory and ethics policy, while promoting the human disease model in the wider scientific community through collaborations on studies using human disease models and to further the science behind the human disease model. • hVIVO has an active publication programme and engages with key opinion leaders and thought leaders to promote the hVIVO platform and its human disease models, their acceptance and the importance of the data produced. hVIVO also ensures its contracts allow full participation in the publication of data. • Infectivity rates are an inherent risk of our business. Infectivity rate is a natural feature of a virus/human interaction. hVIVO exploits current scientific best practice and knowledge to provide the most appropriate circumstances and environment for infection to occur, through this cannot be guaranteed.

Principal risk	Category	Mitigation
<p>Operations and business performance</p> <p>Failure to balance our revenue against demand and lumpy utilisation against a fixed cost base would impact our financial performance.</p> <p>Failure to attract and retain appropriate skills and expertise in specialist areas could impact our ability to emerge into new markets and/or therapeutic areas.</p> <p>Poor operational controls could lead to failure to deliver against promise and would result in reputational impact.</p>		<ul style="list-style-type: none"> Development of market intelligence and customer insight strategies, networks and new collaborations help hVIVO to stay at the forefront of industry developments in a drive to stay ahead of the competition and respond to a rapidly changing market. hVIVO continues to focus on building and diversifying our product and service offering whilst building our business development capability and client pipeline. hVIVO undertakes significant investment in R&D and New Product Development. hVIVO utilises multiple levels of operational control to support successful studies, including a multi-stage funnel for recruitment, trial protocols to support clients objectives, start-up phases and binding contracts to support delivery against client objectives. hVIVO builds credibility with our clients and engenders trust, advocacy and relationship longevity. hVIVO undergoes continuous assessment of our directly employed to fixed staff ratio and look for new services and models to operate efficiently and drive agility. hVIVO provides a dynamic and collaborative environment in which to work. hVIVO supports open communication, including quarterly Company meetings, frequent staff-wide newsletters, and department meetings. hVIVO maintains competitive salary and benefits packages.
<p>Business continuity, infrastructure and scalability</p> <p>There is a risk that our infrastructure systems and processes may not be sufficiently scalable to match our growth ambitions.</p> <p>Rapid expansion of R&D or revenue growth could be constrained by current infrastructure.</p>		<ul style="list-style-type: none"> As we continue to prioritise our goal of being a fit for purpose, cost-effective and agile organisation, we have formalised our approach to our organisational design review to reflect demand and strategic orientation. Regular system and process reviews to ensure that our systems and infrastructure are fit for purpose. Better information through the continued evolution of our reporting to better manage the business, reduce risk of errors and irregularities. Investment in IT system infrastructure and security systems.
<p>Treasury policy and financial risk</p> <p>Failure to comply with current tax laws or incur significant losses due to market factors and/or lumpy utilisation.</p>		<p>Liquidity risk: hVIVO maintains good relationships with its banks, financial institutions with high credit ratings, and its working capital requirements are anticipated via the forecasting and budgetary processes; regular forecasting and reporting is in place to manage liquidity risk.</p> <p>Credit risk: hVIVO is mainly exposed to credit risk from its trade and other receivables, short-term deposits and bank balances. An allowance for impairment is made where there is an identified loss event which, based on previous experience, is evidence of a reduction in recoverability of the cash flows.</p> <p>Foreign currency risk: hVIVO is exposed to minimal foreign currency risk. The functional currency of the Company is Sterling for its sales and the majority of its purchases. hVIVO seeks to negotiate the majority of its contracts with international clients in Sterling; however, where this is not possible, hVIVO will seek to hedge against the foreign currency risk. Some third party supplier purchases are made in Euros and US Dollars, although these are not considered significant.</p>

Board of Directors

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

Jaime Ellertson

Non-Executive Chairman

Jaime Ellertson was appointed Non-Executive Chairman of hVIVO plc in June 2014. Jaime has lead numerous high growth, data and service-driven companies through phases of rapid expansion, both in the private and public arena. Jaime currently holds the position of Chairman and Chief Executive Officer of Everbridge Inc, a provider of multi-dimensional critical communications solutions to leading healthcare, corporate and government organisations globally. He lives in Massachusetts and is a citizen of the United States of America. Jaime has previously served as the Chief Executive Officer, President and a Director of Gomez Inc, a company specialising in monitoring and managing website data and web application performance. During his tenure he led Gomez Inc through an IPO registration that resulted in the successful sale of the company for \$295 million to Compuware Corporation. He served as Chief Executive Officer, President and Director of S1 Corporation Inc, a software provider to the financial services marketplace. Jaime also orchestrated the successful turnaround of Interleaf, Inc, a provider of software tools for e-content management, culminating in its acquisition for \$852 million by BroadVision Inc in 2000. Earlier in his career, he founded several high growth software companies including Openware Technologies Inc, Document Automation Corporation and Purview Technologies Inc. Jaime is currently a Director of PeopleFluent and Everbridge in addition to having held numerous directorships on both public and private US and UK based companies.

Kym Denny

Chief Executive Officer

Kym Denny was appointed CEO of hVIVO Services Limited in December 2010 and became CEO of hVIVO plc in April 2012. Kym has over 15 years' senior management experience of international clinical trials including Phase I to IV clinical operations, project management, drug safety, data management and site management. This experience was gained in a wide range of therapeutic areas including infectious disease and respiratory, CNS, oncology and women's health.

Kym began her career as a Clinical Research Associate at Kendle Research. She went on to found InSite Clinical Trials, a hybrid CRO and site management company in Atlanta, Georgia, USA, and then to the UK where she was appointed to the Board of Profiad Limited where she also oversaw the Clinical Operations function. She later became Managing Director of Harrison Clinical Research and then joined Origin as Head of International Clinical Operations, being promoted to Vice President of Clinical Research when the company was acquired by Constella LLC and later, SRA International.

Graham Yeatman

Chief Financial & Business Officer

Graham Yeatman joined hVIVO Services Limited as Finance Director in May 2011 and became Finance Director of hVIVO plc in April 2012. He was promoted to Chief Financial & Business Officer in January 2015. Graham has significant experience of building businesses for rapid growth and profitability. He is a Chartered Accountant and trained and worked with PricewaterhouseCoopers for 13 years across its audit, tax, consultancy, business process re-engineering and outsourcing divisions. In 2001 he joined buyingTeam Limited (subsequently renamed Proxima) as Finance and Operations Director and was influential in growing the business to become one of the UK's leading purchasing services providers. In 2006 he joined Neuropharm Group plc as Chief Financial Officer. Graham has a first class degree in Economics and Maths from Bristol University.

Dr Trevor Nicholls**Non-Executive Director**

Dr Trevor Nicholls became a Non-Executive Director in May 2014. Trevor has 35 years of experience building international businesses in the life science industry, with a strong focus on genomics and proteomics. He was previously Chairman of Oxford Nanopore Technologies Limited, is currently Chairman of Avacta Group plc and was the Chairman of Activiomics Limited prior to its acquisition by hVIVO. Trevor is also Chief Executive Officer of CABI, a not-for-profit intergovernmental organisation owned by 48 member countries worldwide. Prior to his current role with CABI, he was Chief Commercial Officer for Affymetrix Inc with accountability for global operations, delivering \$330 million revenue with 600 staff across eight locations worldwide. Prior to Affymetrix, Trevor was founding CEO of Oxygen Ltd, a genomics discovery company spun out from the Wellcome Trust Centre for Human Genetics in Oxford. He has also worked for Amersham International (now part of GE Healthcare), McKinsey and Unilever. Trevor has a BA and a DPhil in Biochemistry from the University of York and holds Diplomas from the Institute of Marketing and Institute of Directors.

James F Winschel**Non-Executive Director**

James F Winschel became a Non-Executive Director in October 2014. He is Chairman of the Audit Committee. Mr Winschel retired in June 2014 as Executive Vice President at PAREXEL International Corporation, a US publicly traded healthcare services company with \$1.9 billion in annual service revenue. He previously served as Senior Vice President and Chief Financial Officer of PAREXEL from 2000 to 2013, with responsibility for directing all financial activities, during a period when PAREXEL's revenue grew by \$1.5 billion and market capitalisation increased from \$225 million to \$2.7 billion. In March 2016, James became CFO of Boston-based Hamlin Scientific Corporation. Prior to joining Hamlin, he was the CFO of Novimmune S.A., a Swiss biotechnology company based in Geneva, Switzerland. Earlier in his career, James spent five years at BTM Capital Corporation, a Bank of Tokyo Mitsubishi Ltd. subsidiary, initially as Executive Vice President and Chief Financial Officer for three years before being promoted to President, U.B. Vehicle Leasing, Inc. Prior to these roles, he was the Vice President of Finance at Caremark International, Inc for two years. He spent the previous four years at Whirlpool Financial Corporation, both as the Vice President and Managing Director, Commercial Financing Division and prior to that as the Vice President and Chief Financial Officer. James worked for five years in various roles at General Electric Capital Corporation, in the Transportation and Industrial Financing Division and prior to that at General Electric Company for eleven years. James holds an MBA in Accounting and a BSc in Finance from Syracuse University in the USA.

Dr Mark Warne**Non-Executive Director**

Mark Warne became a Non-Executive Director of hVIVO in April 2016 and will act as Chairman of the Remuneration Committee. He is currently Head of IP Group's Healthcare division, which at the end of December 2015, had shareholdings in 31 companies valued at over £275 million. Mark also represents IP Group on the boards of a number of its portfolio companies, both quoted and private; notably Genomics plc, Cronin Group plc and Crysalin Limited. Mark has been at IP Group since 2008 and has extensive experience in building world-changing healthcare businesses as well as in managing transactions including portfolio company IPOs, financings and M&A. He joined IP Group from pre-clinical drug discovery CRO, Exelgen, where he was Managing Director. Mark spent eight years at Exelgen (formerly known as Tripos Discovery Research) where he also held positions in licensing and strategic affairs, project management and research. He has a PhD in Computational Chemistry, an MSc in Colloid Science and a BSc in Chemistry, all from the University of Bristol. Mark is a Chartered Chemist and member of the Royal Society of Chemistry.

Directors' report

Financial statements

The Directors present their Annual Report and audited Financial Statements for the Company and Group for the year ended 31 December 2015.

Principal activities

hVIVO is a life sciences business pioneering a technology platform of human disease models to accelerate drug discovery and development in respiratory and infectious diseases, including flu, RSV, asthma and common cold. hVIVO has commercialised four disease models, successfully enrolled over 2,000 subjects and conducted over 40 product validation studies for a wide range of industry, government and academic clients and collaborators.

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

Business review and key performance indicators

The Group's results are set out in the consolidated statement of comprehensive income on page 38 and are explained in the financial review on pages 18 and 19. A detailed review of the business, its results and future direction is included in the Chief Executive Officer's statement on pages 02 to 07.

Capital structure

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

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

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

Details of employee share schemes are set out in note 27.

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

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

Research and development

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

Dividends

The Directors do not recommend the payment of a dividend (2014: £nil).

Directors

The Directors of the Company are as follows:

Kym Denny	
Graham Yeatman	
Jaime Ellertson	
David Norwood	Retiring at the Annual General Meeting on 23 May 2016
Alison Fielding	Retiring at the Annual General Meeting on 23 May 2016
Trevor Nicholls	
James Winschel	
Mark Warne	Appointed 19 April 2016

At 31 December 2015, the Directors had the following beneficial interests in the Company's shares:

	31 December 2015 Number	31 December 2014 Number
Executive Directors		
Kym Denny	347,680	347,680
Graham Yeatman	185,200	185,200
Non-Executive Directors		
David Norwood	3,219,520	3,219,520
Jaime Ellertson	25,165	5,423
James Winschel	26,413	—
Alison Fielding	24,320	24,320

Biographical details of the Directors who are not retiring are given on pages 24 and 25.

Directors' interests

The interests of Directors in the shares of the Company are given above and in the Directors' remuneration report on pages 32 to 34.

Directors interests in contracts of significance, other than service contracts are disclosed in note 29 to the financial statements. Information regarding Directors' service contracts is given on page 32 within the Directors' remuneration report.

Third party indemnity provision for Directors

The Company has made qualifying third party indemnity provisions for the benefit of its Directors which were made during the year and remain in force at the date of this report.

Share capital

On 4 March 2015, 438,072 ordinary shares were issued in relation to deferred consideration for the acquisition of Activiomics Limited (233,187 ordinary shares) and an exercise of warrants by Numis Securities Limited (204,885 ordinary shares).

On 13 May 2015, 716,871 ordinary shares were issued in relation to the exercise of employee share options.

On 26 June 2015, 108,604 ordinary shares were issued in relation to the exercise of employee share options.

On 15 December 2015, 9,111,111 ordinary shares were issued via a placing at a price of 225 pence per share raising £20.5 million which, after share issue expense of £0.5 million, gave net consideration of £20.0 million.

During 2015, 25,805 ordinary shares were allotted pursuant to the quarterly purchase of shares by Jaime Ellertson and James Winschel under the terms of their letters of appointment.

As at 31 December 2015, the issued share capital of the Company was:

	Number of ordinary 5p shares	Nominal value £
Issued and fully paid up	78,052,784	3,902,639

The average market price of the Company's ordinary shares at close of business on 31 December 2015 was 231 pence per share.

The maximum share price during the year was 343 pence per share (17 April 2015) and the minimum price was 231 pence per share (31 December 2015).

On 5 January 2016 7,520 new ordinary shares were allotted pursuant to the quarterly purchase of shares by Jaime Ellertson and James Winschel, under the terms of their letters of appointment.

Directors' report continued

Substantial share interests

At 19 April 2016, the Company had been advised or is aware of the following interests of 3% or more in the Company's issued share capital:

	Number of shares	Percentage of issued share capital
Invesco Limited	21,249,382	27.2
IP2IPO Limited	13,063,883	16.7
IP Venture Fund	2,171,371	2.8
Woodford Investment Management LLP	11,037,192	14.1
Lansdowne Partners (UK) LLP	5,816,038	7.5
Ruffer LLP	3,828,538	4.9
Henderson Global Investors Limited	3,338,645	4.3
David Norwood	3,219,520	4.1

Employees

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

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

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

Auditor

Each of the persons who is a Director at the date of approval of this annual report confirms that;

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

This confirmation is given and should be interpreted in accordance with the provisions of s418 of the Companies Act 2006.

Deloitte LLP has expressed its willingness to continue in office as auditors and a resolution to re-appoint them will be proposed at the forthcoming Annual General Meeting.

Annual General Meeting

The Notice convening the Annual General Meeting, which will take place at 10.00am on 23 May 2016 at the Company's registered office, has been sent out to shareholders with the Annual Report. Details of the business to be transacted at the AGM can be found in the Notice.

By order of the Board



Graham Yeatman

Chief Financial & Business Officer

19 April 2016

Corporate governance statement

Principles of corporate governance

As a company admitted to trading on AIM, the Company is not subjected to compliance of the UK Corporate Governance code (the "Code"). The Board has nonetheless taken steps to consider the main provisions of the code insofar as practical and reasonable given the size of the Group and the nature of its operations.

The Company's Board appreciates the value of good corporate governance not only in the areas of accountability and risk management but also as a positive contribution to business performance. It believes that corporate governance involves more than a simple "box ticking" approach to establish whether a company has met the requirements of a number of specific rules and regulations. Rather the issue is one of applying corporate governance principles (including those set out in the Corporate Governance Code for Small and Mid-Size Quoted Companies published by the Quoted Companies Alliance) in a sensible and pragmatic fashion having regard to the individual circumstances of our business. The key objective is to enhance and protect shareholder value.

Board of Directors

During 2015, the Board of hVIVO plc comprised two Executive Directors and five Non-Executive Directors, one of whom is the Chairman. The roles of Chairman and Chief Executive Officer are distinct and are held by different people to ensure a clear division of responsibility. The role of the Non-Executive Directors is to bring valuable judgement and insight to Board deliberations and decisions. The Non-Executive Directors are all experienced and influential individuals whose blend of skills and business experience contributes to the proper functioning of the Board and its Committees, ensuring that matters are fully debated and that no individual or group dominates the Board's decision-making processes.

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

The Board receives regular reports detailing the progress of the Group, the Group's financial position and projections, as well as business development activities and operational issues, together with any other material deemed necessary for the Board to discharge its duties. The Chairman is primarily responsible for the effective operation and chairing of the Board and for ensuring that it receives appropriate information to make informed judgements.

The Board has a formal schedule of matters reserved to it for decision but otherwise delegates specific responsibilities to Committees, as described below. The terms of reference of the Committees are provided on the investor section of the Company's website. The Board is responsible for the review and approval of key policies and decisions in respect of business strategy and operations, Board appointments, budgets and forecasts, items of substantial investment and acquisitions.

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

Board Committees

The Board has established an Audit Committee and a Remuneration Committee with written terms of delegated responsibilities for each.

Audit Committee

The Audit Committee comprises three Non-Executive Directors: James Winschel, who chairs the Committee, Alison Fielding and Trevor Nicholls. Mark Warne will replace Alison Fielding on the Audit Committee. The external auditor, Chief Executive Officer and Chief Financial & Business Officer may be invited to attend Audit Committee meetings and, following each meeting, the Audit Committee and external auditor have the opportunity to meet without the Executive Directors present. The Audit Committee meets at least three times each year for full-year, half-year and audit planning purposes.

The Committee reviewed the half-year and full year results as well as the Half-year Report and Annual Report and Financial Statements prior to their submission to the Board and considered any matters raised by the external auditor. All scheduled Committee meetings were quorate and the conclusions from those meetings were presented to the Board.

In certain circumstances it is permitted by the Board for the auditor to supply non-audit services (for example, in the provision of tax advice). The Audit Committee has approved and monitored the application of this policy in order to safeguard auditor objectivity and independence. The overall fees paid to the auditor are not deemed significant enough to them so as potentially to impair their independence. The auditor is awarded assignments on a competitive basis and the Audit Committee pre-approves all permitted non-audit expenditure incurred and during the year reviews the cost-effectiveness, independence and objectivity of the external auditor. A formal Statement of Independence is received from the external auditor each year.

Remuneration Committee

The Remuneration Committee is chaired by Alison Fielding and comprises all the Non-Executive Directors. Mark Warne will replace Alison Fielding as Chairman of the Remuneration Committee. The Remuneration Committee meets at least once each year.

The Committee is responsible for considering the Executive Directors' and senior management's remuneration packages and makes its recommendations to the Board.

The Chief Executive and Chief Financial & Business Officer may be invited to attend Remuneration Committee meetings, other than when their own remuneration is discussed. No Director is involved in deciding his own remuneration.

Further details of Directors' remuneration are disclosed in the Directors' remuneration report.

Internal control and risk management

The Board acknowledges its responsibility for safeguarding shareholders' investments and the Group's assets. In applying this principle, the Board recognises that it has overall responsibility for ensuring that the Group maintains a system of internal control that provides it with reasonable assurance regarding effective and efficient operations, internal financial control and compliance with laws and regulations. The system of internal control is designed to manage rather than eliminate the risk of failure to achieve business objectives, and can only provide reasonable and not absolute assurance against material misstatement or loss.

Through the Audit Committee, the Directors have reviewed the effectiveness of the internal controls. The key features of the internal control environment are described below:

- **control procedures and environment** – the Group has an organisational structure with clearly drawn lines of accountability and authority. Employees are required to follow well-defined internal procedures and policies appropriate to the business and their position within the business and management promotes the highest levels of professionalism and ethical standards;
- **identification and evaluation of risks** – the Group employs Executive Directors and senior management with the appropriate knowledge and experience required for a medical and scientific research group. Identification and evaluation of risk is a continuous process;
- **financial information** – the Group prepares detailed budgets and working capital forecasts. These are based upon the strategy and business planning of the Group and are approved by the Board. Detailed management accounts and working capital re-forecasts are reviewed at least quarterly for each Board meeting, with any variances from budget investigated thoroughly and a summary provided to the Board. Annual Reports, Preliminary Statements and Half-year Reports prepared by the Group are reviewed by the Audit Committee prior to approval by the Board; and
- **monitoring** – the Board monitors the activities of the Group through the supply of reports from various areas of the business as contained in the Board papers. The Executive Committee performs a more detailed review, taking corrective action if required. The Board, through the Audit Committee, reviews the effectiveness of the systems of internal control.

Given the Group's relative small size, the Board does not consider it either necessary or practical at present to have its own internal audit function. The Board will continue to monitor the requirement to have an internal audit function.

Communication with shareholders

The Board attaches great importance to communication with both institutional and private shareholders.

Regular communication is maintained with all shareholders through Company announcements, the Annual Report and Financial Statements, Preliminary Statements and Half-year Report.

The Directors seek to build on a mutual understanding of objectives between the Company and its shareholders, especially considering the long-term nature of the business. Institutional shareholders are in contact with the Directors through presentations and meetings to discuss issues and to give feedback regularly throughout the year. With private shareholders this is not always practical. The Board, therefore, likes to use the Company's Annual General Meeting as the opportunity to meet private shareholders who are encouraged to attend, after which the Chief Executive Officer will give a presentation on the activities of the Group. Following the presentation there will be an opportunity to ask questions of the Executive Directors on a formal and informal basis and to discuss development of the business.

The Company operates a website at www.hvivo.com. The website contains details of the Group and its activities, regulatory announcements and Company announcements, Annual Reports and Half-year Reports, and the Terms of Reference of the Audit and Remuneration Committees.

Going concern

As disclosed in note 2 to the Consolidated Financial Statements, having made relevant and appropriate enquiries, including consideration of the Company and Group current resources and working capital forecasts, the Directors have a reasonable expectation that, at the time of approving the Financial Statements, the Company has adequate resources to continue in operational existence for the foreseeable future. Accordingly, the Board continues to adopt the going concern basis in preparing the Financial Statements.

Directors' remuneration report

Introduction

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

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

Remuneration practice overview

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

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

Our approach is designed to offer rewards that:

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

Our reward strategy includes:

- base salaries which are aimed at above average for the UK life sciences and biotechnology sectors and linked to market conditions, Company and individual performance;
- a discretionary performance based bonus linked to stretch Company and individual performance goals measured through business planning and KPI measures as well as individual performance appraisal processes; and
- share incentives, issued to our most senior executives and certain individuals who have been considered key to incentivise and retain in certain stages of the Company's growth.

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

Executive Directors

Kym Denny has a service agreement with hVIVO plc dated 26 April 2012, with continuous employment from 28 September 2009. Her appointment is terminable on six months' notice by either party.

Graham Yeatman has a service agreement with hVIVO plc dated 15 April 2015, with continuous employment from 3 May 2011. His appointment is terminable on six months' notice by either party.

Non-Executive Directors

The Non-Executive Directors have entered into letters of appointment with the Company, with the Board determining any fees paid. The appointments are terminable on three months' notice by either party. The Non-Executive Directors do not participate in the Group's pension, bonus or option schemes. Options previously awarded to Trevor Nicholls by Activiomics Limited were, following acquisition, exchanged for hVIVO options on a like-for-like basis.

Remuneration

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

Salary

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

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

Benefits

During 2016, the Company is very excited to be investing in a new innovative flexible benefit platform which will provide a much more engaging approach to the overall management and visibility of total reward for employees as well as introducing benefit enhancements this year for all employees of life assurance and healthcare solutions.

Bonuses

The timing and amount of bonuses are decided by the Remuneration Committee with reference to the individual's performance and contribution to the Group. The maximum bonus that can be earned by an Executive Director is 100% of base salary.

Pensions

The Group operates a Group personal pension scheme which is a defined contribution scheme. Under the scheme rules, the Group pays an employer pension contribution of between 3% and 9% of base salary. The scheme is open to the Executive Directors and employees.

Directors' remuneration

The Directors received the following remuneration during the year:

	Salary and fees ¹ £'000	Taxable benefits £'000	Bonus £'000	2015 total excluding pensions £'000	2015 pensions £'000	2014 total excluding pensions £'000	2014 pensions £'000
Kym Denny	225	32	70	327	19	226	14
Graham Yeatman	212	—	56	268	18	157	13
Executive Directors	437	32	126	595	37	383	27
Jaime Ellertson ²	132	—	—	132	—	69	—
Alison Fielding	20	—	—	20	—	7	—
Trevor Nicholls	20	—	—	20	—	16	—
David Norwood	20	—	—	20	—	25	—
James Winschel ³	50	—	—	50	—	13	—
Duncan Peyton	—	—	—	—	—	6	—
Charles Winward	—	—	—	—	—	5	—
Non-Executive Directors	242	—	—	242	—	141	—
Total	679	32	126	837	37	524	27

1 Salary and fees including travel allowances.

2 Jaime Ellertson's disclosed remuneration includes an amount which is contractually committed by him quarterly to purchase shares of hVIVO plc.

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

Directors' remuneration report continued

Share options

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

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

The share scheme was established immediately following the Company's acquisition of the entire issued share capital of hVIVO Services Limited (formerly Retroscreen Virology Limited) on 20 April 2012. The share scheme replicates the terms of the hVIVO Share Option Scheme (the "Old Share Scheme") which was operated by hVIVO Services Limited prior to the acquisition. Options over ordinary shares in hVIVO Services Limited outstanding under the Old Share Scheme at the time of the acquisition were exchanged by option holders for options on the same terms.

On 21 April 2015 hVIVO implemented a new share scheme available to Executive Directors and key management. As participants in the new share scheme, hVIVO granted 200,148 options over ordinary shares of 5.0 pence each in the Company to the Executive Directors with an exercise price of £3.37 per share under a new share option plan.

	Options as at 31 December 2014	Number of options granted during the year	Options as at 31 December 2015	Date of grant	Expiry of option	Exercise price	Percentage vested
Kym Denny	145,540	—	145,540	13 Jan 2010	12 Jan 2020	6.25p	100
Kym Denny	1,366,320	—	1,366,320	23 Dec 2011	22 Dec 2021	8.15p	100
Kym Denny	—	111,193	111,193	21 Apr 2015	20 Apr 2025	337.25p	—
Graham Yeatman	644,600	—	644,600	23 Dec 2011	22 Dec 2021	8.15p	100
Graham Yeatman	—	88,955	88,955	21 Apr 2015	20 Apr 2025	337.25p	—
Trevor Nicholls ¹	26,540	—	26,540	3 Mar 2014	18 Dec 2022	101.63p	100

¹ Under the terms of the agreement to purchase 100% of the ordinary shares of Activiomics Limited, the options in Activiomics Limited were exchanged for options in the Company on a like-for-like basis.

On 26 April 2012, following the share-for-share exchange and 20 for 1 share split, the original options on shares in hVIVO Services Limited were exchanged for new options on shares in the Company on an equivalent basis.

No options held by the Directors were exercised or lapsed during the year.

Directors' responsibilities statement

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

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

Under company law the Directors must not approve the Financial Statements unless they are satisfied that they give a true and fair view of the state of affairs of the Group and the Company and of the profit or loss of the Group for that period. In preparing each of the Group and Company Financial Statements, the Directors are required to:

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

The Directors are responsible for keeping adequate accounting records that are sufficient to show and explain the Group's and the Company's transactions and disclose with reasonable accuracy at any time the financial position of the Group and the Company and enable them to ensure that the Financial Statements comply with the Companies Act 2006. They are also responsible for safeguarding the assets of the Group and the Company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

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

Independent auditor's report

to the members of hVIVO plc

We have audited the financial statements of hVIVO plc for the year ended 31 December 2015 which comprise Consolidated statement of comprehensive income, Consolidated and Company statement of financial position, Consolidated statement of changes in equity, Consolidated and Company statement of cash flows and the related notes 1 to 32. The financial reporting framework that has been applied in their preparation is applicable law and International Financial Reporting Standards (IFRSs) as adopted by the European Union and, as regards to the parent company financial statements, as applied in accordance with the provisions of the Companies Act 2006.

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

Respective responsibilities of directors and auditor

As explained more fully in the Directors' Responsibilities Statement, the directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view. Our responsibility is to audit and express an opinion on the financial statements in accordance with applicable law and International Standards on Auditing (UK and Ireland). Those standards require us to comply with the Auditing Practices Board's Ethical Standards for Auditors.

Scope of the audit of the financial statements

An audit involves obtaining evidence about the amounts and disclosures in the financial statements sufficient to give reasonable assurance that the financial statements are free from material misstatement, whether caused by fraud or error. This includes an assessment of: whether the accounting policies are appropriate to the group's and the parent company's circumstances and have been consistently applied and adequately disclosed; the reasonableness of significant accounting estimates made by the directors; and the overall presentation of the financial statements. In addition, we read all the financial and non-financial information in the annual report to identify material inconsistencies with the audited financial statements and to identify any information that is apparently materially incorrect based on, or materially inconsistent with, the knowledge acquired by us in the course of performing the audit. If we become aware of any apparent material misstatements or inconsistencies we consider the implications for our report.

Opinion on financial statements

In our opinion:

- the financial statements give a true and fair view of the state of the group's and of the parent company's affairs as at 31 December 2015 and of the group's loss for the year then ended;
- the group financial statements have been properly prepared in accordance with IFRSs as adopted by the European Union;
- the parent company financial statements have been properly prepared in accordance with IFRSs as adopted by the European Union and as applied in accordance with the provisions of the Companies Act 2006; and
- the financial statements have been prepared in accordance with the requirements of the Companies Act 2006.

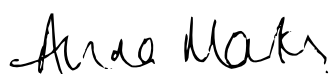
Opinion on other matters prescribed by the Companies Act 2006

In our opinion the information given in the Strategic Report and the Directors' Report for the financial year for which the financial statements are prepared is consistent with the financial statements.

Matters on which we are required to report by exception

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

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

**Anna Marks FCA (Senior Statutory Auditor)**

for and on behalf of Deloitte LLP
Chartered Accountants and Statutory Auditor
Reading, United Kingdom

19 April 2016

Consolidated statement of comprehensive income

for the year ended 31 December 2015

	Note	2015 £'000	2014 £'000
Revenue		7,717	18,472
Cost of sales		(5,266)	(12,999)
Gross profit		2,451	5,473
Other income	6	1,187	—
Research and development expense		(10,199)	(10,733)
Provision against virus inventory	17	(1,617)	(58)
Administrative expense		(13,671)	(17,730)
Share of loss of associate	16	(146)	—
Loss from operations	7	(21,995)	(23,048)
Finance income	9	387	358
Finance costs	10	(17)	(15)
Loss before taxation		(21,625)	(22,705)
Taxation	11	3,716	4,269
Loss for the year		(17,909)	(18,436)
Other comprehensive income			
Items that may be reclassified subsequently to profit or loss:			
Share of other comprehensive income of associate		(5)	—
Exchange differences arising on translating foreign operations		1	—
Total comprehensive loss for the year attributable to owners of the parent		(17,913)	(18,436)
Loss per share – basic (pence)	12	(26.0p)	(31.3p)
Loss per share – diluted (pence)	12	(26.0p)	(31.3p)

All activities relate to continuing operations.

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

Consolidated statement of financial position

At 31 December 2015

	Note	2015 £'000	2014 £'000
Assets			
Non-current assets			
Goodwill	13	1,722	1,722
Intangible assets	14	3,030	3,333
Property, plant and equipment	15	2,679	3,153
Investment in associate	16	14,254	—
		21,685	8,208
Current assets			
Inventories	17	2,141	3,731
Current intangible asset	18	2,935	—
Trade and other receivables	19	2,642	2,904
Research and development tax credit receivable		4,101	3,806
Short-term deposits	20	37,031	28,007
Cash and cash equivalents	21	14,205	22,826
		63,055	61,274
Total assets		84,740	69,482
Equity and liabilities			
Equity			
Share capital	26	3,903	3,383
Share premium account		93,145	72,498
Share-based payment reserve		144	249
Merger reserve		4,199	4,199
Other reserve		211	921
Retained deficit		(37,979)	(20,066)
Total equity		63,623	61,184
Non-current liabilities			
Other payables	23	475	550
Provisions	24	3,140	3,130
		3,615	3,680
Current liabilities			
Trade and other payables	22	17,502	4,618
		17,502	4,618
Total liabilities		21,117	8,298
Total liabilities and equity		84,740	69,482

The Consolidated Financial Statements of hVIVO plc (registered company number 08008725) on pages 38 to 63 were approved and authorised for issue by the Board on 19 April 2016 and signed on its behalf by:



Kym Denny

Chief Executive Officer



Graham Yeatman

Chief Financial & Business Officer

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

Consolidated statement of changes in equity

for the year ended 31 December 2015

	Share capital £'000	Share premium account £'000	Share-based payment reserve £'000	Merger reserve £'000	Other reserve £'000	Retained deficit £'000	Total equity £'000
As at 31 December 2013	2,686	37,363	239	4,199	—	(1,630)	42,857
Proceeds from shares issued:							
Acquisition of subsidiary	50	2,987	—	—	921	—	3,958
Issue of new shares	—	15	—	—	—	—	15
Placing net of related expenses	647	32,133	—	—	—	—	32,780
Total transactions with owners in their capacity as owners	697	35,135	—	—	921	—	36,753
Loss for the year	—	—	—	—	—	(18,436)	(18,436)
Share-based payment expense	—	—	10	—	—	—	10
As at 31 December 2014	3,383	72,498	249	4,199	921	(20,066)	61,184
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	(183)	—	(710)	—	20,274
Loss for the year	—	—	—	—	—	(17,909)	(17,909)
Exchange differences on translation of foreign assets	—	—	—	—	—	(4)	(4)
Share-based payment expense	—	—	78	—	—	—	78
As at 31 December 2015	3,903	93,145	144	4,199	211	(37,979)	63,623

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

Consolidated statement of cash flows

for the year ended 31 December 2015

	Note	2015 £'000	2014 £'000
Net cash used in operating activities	32	(9,846)	(16,599)
Cash flows from investing activities			
Acquisition of intangible assets		(15)	(148)
Acquisition of property, plant and equipment		(869)	(1,355)
Increase in balances on short-term deposit		(9,024)	(5,507)
Investment in associate		(9,405)	67
Interest received		398	361
Net cash used in investing activities		(18,915)	(6,582)
Cash flows from financing activities			
Net proceeds from issue of shares		20,205	32,780
Other payables repaid		(75)	(75)
Net cash generated from financing activities		20,130	32,705
Net (decrease)/increase in cash and cash equivalents		(8,631)	9,524
Exchange gain/(loss) on cash and cash equivalents		10	(8)
Cash and cash equivalents at the start of year		22,826	13,310
Cash and cash equivalents at the end of year		14,205	22,826

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

Notes to the consolidated financial statements

1. General information

hVIVO plc (the "Company") and its subsidiaries (together, the "Group") is a life sciences business pioneering a technology platform of human disease models to accelerate drug discovery and development in respiratory and infectious diseases, including flu, RSV, asthma and common cold. hVIVO has commercialised four disease models, successfully enrolled over 2,000 subjects and conducted over 40 product validation studies for a wide range of industry, government and academic clients and collaborators. The Group carries out its core activities from the United Kingdom. Sales and marketing support is provided by the US based subsidiary of the Company, hVIVO Inc.

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

On 14 April 2015 the Company changed its name to hVIVO plc (formerly Retroscreen Virology Group plc). The Company was incorporated on 27 March 2012 and on 20 April 2012 ownership of hVIVO Services Limited (formerly Retroscreen Virology Limited) was transferred to the Company in exchange for the issue of ordinary shares in the Company (hereinafter referred to as the "Reorganisation"). The Reorganisation is not deemed to be a business combination within the scope of IFRS 3 Business Combinations and accordingly these Consolidated Financial Statements reflect the merger basis of accounting whereby:

- the carrying amount of assets and liabilities included are based on the historical carrying amounts of such assets and liabilities recognised by hVIVO Services Limited;
- the results and cash flows are presented as though the reorganisation occurred on 1 January 2012 and reflects the results and cash flows of hVIVO Services Limited; and
- the amount recognised in equity is based on the historical carrying amounts recognised by hVIVO Services Limited. However, the share capital balance is adjusted to reflect the equity structure of the outstanding stock of the Company, and any corresponding differences are reflected as an adjustment to additional paid in capital.

2. Summary of significant accounting policies

The principal accounting policies applied in the preparation of these Consolidated Financial Statements are set out below. These policies have been consistently applied to all the years presented, unless otherwise stated.

Basis of preparation

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

The Company has elected to take the exemption under section 408 of the Companies Act 2006 not to present the Parent Company's statement of comprehensive income. The Parent Company's result for the year was a loss of £176,000 (2014: loss £325,000).

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

The Financial Statements have been prepared under the historical cost convention.

Going concern

The Group's business activities, together with the factors likely to affect its future development, performance and position are set out in the Strategic Report and Directors' Report on pages 01 to 23 and pages 26 to 29.

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 2015 the Group had short-term deposits, cash and cash equivalents of £51.2 million (2014: £50.8 million) and net current assets of £45.6 million (2014: £56.7 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.

Basis of consolidation

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

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

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

Business combinations

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

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

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

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

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

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

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

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

Notes to the consolidated financial statements continued

2. Summary of significant accounting policies continued

Investment in associates

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

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

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

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

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

Foreign currencies

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

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

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

Revenue recognition

Revenue is recognised at the fair value of the consideration received or receivable for sale of goods and services in the ordinary course of business and is shown net of Value Added Tax.

Service revenues

The Group primarily earns revenues by undertaking client clinical services engagements. A client clinical service engagement typically comprises a number of quarantines. Each quarantine lasts two to three weeks, but the timeline of work involved in building up to undertaking a quarantine is in the range of three to twelve months. Whether a client clinical service engagement is for one quarantine or for a number of quarantines, the overall timeline of the engagement is much the same, apart from the additional time for the quarantines themselves and the time lags in between quarantines (with some volunteer cohorts offset in parallel and some sequential), as much of the upfront work is the same whether for one or a number of quarantines. Client clinical service revenue is recognised on a percentage of completion method using output measures.

Depending on the contractual terms, revenue is recognised based on the level of work completed to date in respect of each individual element of the client clinical service contract.

Contracts generally contain provisions for renegotiation in the event of changes in the scope, nature, duration, volume of services or conditions of the contract. Renegotiated amounts are recognised as revenue by revision to the total contract value arising as a result of an authorised customer change order. Provisions for losses to be incurred on contracts are recognised in full in the period in which it is determined that a loss will result from performance of the contractual arrangement.

The difference between the amount of revenue recognised and the amount invoiced on a particular contract is included in the consolidated statement of financial position as deferred income. Normally amounts become billable in advance upon the achievement of certain milestones, in accordance with pre-agreed payment schedules included in the contract or on submission of appropriate detail. Any cash payments received as a result of this advance billing are not representative of revenue earned on the contract as revenues are recognised over the period during which the specified contractual obligations are fulfilled. Amounts included in deferred income are expected to be recognised within one year and are included within current liabilities.

In the event of contract termination, if the value of work performed and recognised as revenue is greater than aggregate milestone billings at the date of termination, cancellation clauses provide for the Group to be paid for all work performed to the termination date.

Licencing revenues

Where licencing arrangements have a single contracted deliverable, such as the delivery of a license for study data, revenue is recognised when the Group has transferred to the buyer the significant risks and rewards of ownership of the deliverable, the Group no longer has managerial involvement or effective control of the deliverable, the amount of revenue and costs associated with the transaction can be measured reliably, it is probable that the Group will receive future economic benefits associated with the transaction and costs incurred can be reliably measured. Licence revenue for such arrangements is therefore generally recognised on handover of the deliverable. Until this point in time any amount invoiced in respect of the arrangement is presented in the consolidated statement of financial position as deferred income. Costs associated with development of the study data are capitalised as a current intangible asset from the point that it is probable future economic benefits will be generated.

Internally generated intangible assets – research and development expenditure

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

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

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

Intangible assets

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

Property, plant and equipment

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

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

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

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

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

Notes to the consolidated financial statements continued

2. Summary of significant accounting policies continued

Impairment of tangible and intangible assets

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

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

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

Impairment of goodwill

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

Inventories

Inventories are reported at the lower of cost (purchase price and/or production cost) and net realisable value. Net realisable value is the estimated selling price in the ordinary course of business, less estimated costs of completion and applicable variable selling expenses.

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

Financial instruments

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

Trade receivables

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

Cash and cash equivalents

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

Short-term deposits

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

Equity instruments

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

Trade and other payables

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

Borrowings

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

Current and deferred tax

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

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

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

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

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

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

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

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

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

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

Operating leases

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

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

Notes to the consolidated financial statements continued

2. Summary of significant accounting policies continued

Share-based payment transactions

Options

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

The total amount to be expensed is determined by reference to the fair value of the options granted at the grant date. The fair value excludes the effect of non-market-based vesting conditions. Details regarding the determination of the fair value of equity-settled share-based transactions are set out in note 27.

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

Warrants

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

Pension costs

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

Provisions

Provisions for dilapidations and onerous lease commitments are recognised when: the Group has a present legal or constructive obligation as a result of past events, it is probable that the Group will be required to settle that obligation and a reliable estimate can be made of the amount of the obligation. The amount recognised as a provision is the best estimate of the consideration required to settle the present obligation at the end of the reporting period, taking into account the risks and uncertainties surrounding the obligation. Where a provision is measured using the cash flows estimated to settle the present obligation, its carrying amount is the present value of those cash flows (when the effect of the time value of money is material). When some or all of the economic benefits required to settle a provision are expected to be recovered from a third party, a receivable is recognised as an asset if it is virtually certain that reimbursement will be received and the amount of the receivable can be measured reliably.

3. Critical accounting estimates and judgements

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

Revenue, deferred income and accrued income

Revenue is recognised based on the level of work completed to date under the percentage of completion method. The recognition of revenue (and hence the related deferred and accrued income balances) requires management to make estimates in relation to the level of work done to date and assumptions of the costs to complete each project.

At each period end, management reviews each individual contract to assess whether any anticipated losses should be recognised immediately.

hVIVO sold intellectual property licences for the value of £6.4 million during the year and in assessing the appropriate revenue recognition policy, management reviewed the contracted deliverables associated with the transaction and then made a judgement that it was not appropriate to recognise revenue over time but instead at a point in time. Accordingly, revenues associated with licencing arrangements have been deferred until the delivery of the intellectual property.

Impairment of intangible assets and goodwill

The Group's balance sheet includes goodwill and intangible assets. Impairment exists when the carrying value of an asset or cash generating unit exceeds its recoverable amount, which is the higher of fair value less costs of disposal and its value in use. Determining whether an asset is impaired requires estimation of the fair value of the asset or cash generating unit or the estimation of the value in use of the cash generating unit to which the asset has been allocated.

Virus inventory

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

Leasehold provision

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

Research and development tax credit

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

Control over equity investments

In November 2015, the Group acquired an equity interest in PrEP Biopharm Limited. Assessing the appropriate accounting treatment for that investment, particularly whether hVIVO controls PrEP Biopharm Limited, required judgement which is explained in note 16.

The conclusion from applying the requirements in IFRS 10 Consolidated Financial Statements was that PrEP Biopharm Limited is not controlled by hVIVO, but is an associate over which hVIVO has significant influence. Accordingly, hVIVO's uses the equity method to account for its interest in PrEP Biopharm Limited.

The differences between consolidating a controlled entity and applying the equity method are significant. The equity method requires hVIVO to recognise its share of profits and losses and other changes in the net assets of PrEP Biopharm Limited. Had hVIVO determined that it controlled PrEP Biopharm Limited the entity would have presented all of the expenses, assets and liabilities of PrEP Biopharm Limited as part of the hVIVO Group, with an appropriate minority interest.

Following the investment, PrEP Biopharm Limited entered into contractual arrangements with hVIVO (see note 29). Had the results of PrEP Biopharm Limited been consolidated as part of the hVIVO Group, revenue associated with these contracts would eliminate on consolidation.

4. Interpretations of accounting standards

Amendments to published standards effective for the year ended 31 December 2015

During the year no amendments to standards that became effective during the year were material to the Group.

Standards adopted early by the Group

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

New and revised IFRSs in issue but not yet effective

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

- IFRS 9 Financial Instruments
- IFRS 14 Regulatory Deferral Accounts
- IFRS 15 Revenue from Contracts with Customers
- IFRS 16 Leases
- IFRS 11 (amendments) Account for Acquisitions of Interests in Joint Operations
- IAS 16 and IAS 38 (amendments) Clarification of Acceptable Methods of Depreciation and Amortisation
- IAS 19 (amendments) Defined Benefit Plans: Employee Contributions
- IAS 27 (amendments) Equity Method in Separate Financial Statements
- IFRS 10 and IAS 28 (amendments) Sale or Contribution of Assets between an Investor and its Associate or Joint Venture
- IFRS 5 (annual improvements cycle 2012-2014) Non-current Assets Held for Sale and Discontinued Operations
- IFRS 7 (annual improvements cycle 2012-2014) Financial Instruments: Disclosures
- IAS 19 (annual improvements cycle 2012-2014) Employee Benefits
- IAS 34 (annual improvements 2012-2014) Interim Financial Reporting

The Directors are of the opinion, with the exception of IFRS 15 and IFRS 16, that the application of these standards is unlikely to have any significant impact, other than increased disclosures, on the Financial Statements of the Group or Company. The impact of adoption of IFRS 15 Revenue from Contracts with Customers and IFRS 16 Leases is under review.

Notes to the consolidated financial statements continued

5. 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 2015 the Group had two customers who generated revenues greater than 10% of total revenue. These customers generated 59% and 28% of revenue.

During the year ended 31 December 2014 the Group had five customers who generated revenues greater than 10% of total revenue. These customers generated 28%, 22%, 16%, 15% and 11% of revenue.

Revenue from related party transactions totalled £200,000 in 2015 (2014: £nil) as disclosed in note 29.

6. Other income

Other income includes £0.8 million in respect of an R&D Expenditure Credit (RDEC) claim for 2014 which was submitted to HM Revenue & Customs during 2015 and subsequently paid. No such claims for RDEC had been submitted in prior periods and therefore the asset was not recognised in the 2014 period. Additionally, £0.4 million has been accrued in respect of the 2015 period. The Group classifies such RDEC claims as a government grant where amounts receivable as compensation for expenses or losses already incurred are recognised in the consolidated statement of comprehensive income in the period in which they become receivable.

7. Loss from operations

Loss before tax is stated after charging:

	Year ended 31 December 2015 £'000	Year ended 31 December 2014 £'000
Employee benefit expense (note 8)	15,809	16,440
Recruitment and other human resources	672	890
Agency and interim consultants	1,611	4,514
Premises and equipment	2,507	3,931
Volunteer costs	1,695	2,893
Inventories used	1,140	1,407
Virus inventory provision (note 17)	1,617	58
Insurance	271	258
Professional fees	1,080	1,870
Marketing	123	137
Information technology, including telecommunications	1,318	1,940
Depreciation of property, plant and equipment	1,342	1,221
Impairment of property, plant and equipment	—	672
Amortisation of intangible assets	318	435
Dilapidations and onerous lease expense (note 24)	1,003	3,020

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

	Year ended 31 December 2015 £'000	Year ended 31 December 2014 £'000
Auditor fee:		
Fees payable to the Company's auditor for audit of the Company's annual Financial Statements	50	33
Fees payable to the Company's auditor and its associates for other services		
– the audit of the Company's subsidiaries pursuant to legislation	50	38
Total audit fees	100	71
Audit-related fees – audit-related assurance services	20	135
Total audit and audit-related fees	120	206
All other fees – other services	–	12
Total non-audit fees	–	12
	120	218

8. Employees

	Year ended 31 December 2015 Number	Year ended 31 December 2014 Number
The average number of people (including Executive Directors) employed was:		
Management, administration and business development	53	42
hVIVO platform operation	244	348
Discovery and innovation	19	7
	316	397

	Year ended 31 December 2015 £'000	Year ended 31 December 2014 £'000
The aggregate employee benefit expense comprised (including Directors):		
Wages and salaries	13,697	14,609
Social security costs	1,451	1,336
Pension cost – defined contribution plans	583	485
Share option expense	78	10
	15,809	16,440

The remuneration of the Executive Directors, who are the key management personnel of the Group, is shown within note 29.

Notes to the consolidated financial statements continued

9. Finance income

	Year ended 31 December 2015 £'000	Year ended 31 December 2014 £'000
Interest received	387	358

10. Finance costs

	Year ended 31 December 2015 £'000	Year ended 31 December 2014 £'000
Other bank charges	17	15

11. Taxation

	Year ended 31 December 2015 £'000	Year ended 31 December 2014 £'000
Current tax:		
Current year research and development tax credit	(3,749)	(3,806)
Adjustments in respect of previous periods	31	(143)
Foreign current tax	2	—
Deferred tax:		
Origination and reversal of temporary timing differences	—	(320)
	(3,716)	(4,269)

Corporation tax is calculated at 20.25% (2014: 21.49%) 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	(21,625)	(22,705)
Tax at the UK corporation tax rate of 20.25% (2014: 21.49%)	(4,379)	(4,880)
Expenses not deductible in determining taxable profit	129	160
Income not taxable for tax purposes	(595)	—
Fixed asset timing differences not recognised	8	57
Current year research and development tax credit	(1,542)	(1,707)
Movement in unrecognised deferred tax asset	2,137	1,700
Temporary timing differences not recognised	495	544
Adjustments in respect of prior periods	31	(143)
Tax for the year	(3,716)	(4,269)

Factors affecting current and future taxation

The rate of UK corporation tax for the period to 31 March 2015 was 21% and 20% with effect from 1 April 2015. It will then fall to 19% from 1 April 2017, and 17% from 2020.

As at 31 December 2015, the Group had tax losses available for carry forward of approximately £22.76 million (2014: £13.91 million). The Group has not recognised deferred tax assets of £4.1 million (2014: £3.45 million) relating to carried forward losses and £0.28 million in respect of other temporary differences (2014: £nil). These deferred tax assets have not been recognised as the Group's management considers that there is insufficient future taxable income, taxable temporary differences and feasible tax-planning strategies to utilise all of the cumulative losses and therefore it is probable that the deferred tax assets will not be realised in full. If future income differs from current projections, this could significantly impact the tax charge or benefit in future periods.

12. Earnings per share (EPS)

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

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

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

	Year ended 31 December 2015 £'000	Year ended 31 December 2014 £'000
Earnings		
Loss for the year	(17,909)	(18,436)
Number of shares		
Weighted average number of ordinary shares for the purposes of basic EPS	68,943,581	58,839,405
Effect of dilutive potential ordinary shares:		
– share options	–	–
Weighted average number of ordinary shares for the purposes of diluted EPS	68,943,581	58,839,405

In the current year, 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.

13. Goodwill

	2015 £'000	2014 £'000
At 1 January	1,722	–
Recognised on acquisition of subsidiary	–	1,722
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 2015, the recoverable amount of the cash generating unit was considered to be significantly in excess of its book value.

14. Intangible assets

	2015 £'000	2014 £'000
At 1 January	3,333	1,079
Additions at cost	15	148
Recognised on acquisition of subsidiary	–	2,541
Amortisation charge for the year	(318)	(435)
At 31 December	3,030	3,333

Intangible assets comprise software and acquired intellectual property.

Notes to the consolidated financial statements continued

15. Property, plant and equipment

	Leasehold improvements £'000	Plant and machinery £'000	Computer equipment £'000	Total £'000
Cost:				
At 31 December 2013	1,692	2,513	870	5,075
Additions	727	455	173	1,355
Acquisition of subsidiary	—	22	2	24
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
Accumulated depreciation:				
At 31 December 2013	382	711	315	1,408
Charge for the year	293	650	278	1,221
Impairment charge	672	—	—	672
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
Carrying amount:				
At 31 December 2013	1,310	1,802	555	3,667
At 31 December 2014	1,072	1,629	452	3,153
At 31 December 2015	824	1,554	301	2,679

16. Investment in associate

	2015 £'000
As at 1 January	—
Additions	14,405
Loss after tax recognised in the consolidated statement of comprehensive income	(146)
Share of other comprehensive loss of associate	(5)
As at 31 December	14,254

On 1 November 2015 the Company acquired 62.62% of the share capital of PrEP Biopharm Limited ("PrEP Biopharm") for cash consideration of £14.0 million, of which £5.0 million was deferred 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 is a UK based development stage biopharmaceutical company which is developing infectious disease products. At the same time as the investment, PrEP Biopharm entered into contractual arrangements with hVIVO Services Limited to the value of £10.0 million (see note 29).

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

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

Under the terms of the ISHA, hVIVO has appointed two of the current four Directors of PrEP Biopharm, including the Chair, with equal votes and no casting vote. Accordingly, hVIVO does not control the Board. In addition, it is anticipated that PrEP Biopharm will appoint an additional one or two Non-Executive Directors in the short term.

The terms of the ISHA exclude the hVIVO Directors from any Board consideration and decision making on the hVIVO contracts. Under the terms of the PrEP Biopharm transaction, PrEP Biopharm contracted with hVIVO Services Limited for the delivery of hVIVO owned intellectual property in flu and asthma under licencing arrangements and also to conduct a Phase II durability study for a total consideration of £10.0 million. The hVIVO contracts with PrEP Biopharm are priced on an arms-length basis and with normal terms.

hVIVO has concluded that despite having significant influence, the terms of the ISHA mean that it does not have the power to direct the relevant activities of PrEP Biopharm. Accordingly, hVIVO's investment in PrEP Biopharm has been accounted for as an investment in an associate.

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.

	2015 £'000
Current assets	15,298
Non-current assets	5,076
Current liabilities	(123)
Net assets	20,251
Interest in the associate	12,681
Goodwill	1,573
Carrying amount of the Group's interest in the associate	14,254

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

Its loss of £280,000 for the period ending 31 December 2015 consisted of £215,000 of R&D expenditure and £65,000 of administrative expenditure.

17. Inventories

	31 December 2015 £'000	31 December 2014 £'000
Laboratory and clinical consumables	33	67
Virus – finished goods	2,108	2,212
Virus – work in progress	—	1,452
	2,141	3,731

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 (2014: £nil) was recognised against the carrying value of "Virus – finished goods". During 2013/14 management developed two separate strains of H3N2 flu virus for use in both client 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.

As at 31 December 2014, a provision in full of £1.3 million against the carrying value of "Virus – work in progress" was recognised relating to a virus to be used commercially where the new human disease models have not yet demonstrated technical feasibility. As at 31 December 2015, the provision has increased by £3,000 as further costs were incurred developing the virus strain during the year.

18. Current intangible asset

	2015 £'000	2014 £'000
At 1 January	—	—
Additions at cost	2,935	—
At 31 December	2,935	—

During 2015 hVIVO commenced a clinical trial programme with a view to the study data generating future economic benefit through licencing arrangements. Accordingly, the costs of performing these studies have been capitalised. On 1 November 2015, PrEP Biopharm Limited contracted to licence the study data for the flu and asthma studies (see note 29). The study data is forecast to complete and be provided to PrEP Biopharm Limited during 2016, at which point these costs will be amortised through cost of sales.

Notes to the consolidated financial statements continued

19. Trade and other receivables

	31 December 2015 £'000	31 December 2014 £'000
Trade receivables	551	446
VAT recoverable	—	295
Other receivables	405	667
Prepayments	1,274	1,334
Accrued income	412	162
	2,642	2,904

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

The Group recognises an allowance for doubtful debts against trade receivables based on estimated irrecoverable amounts determined by reference to past default experience of the counterparty and an analysis of the counterparty's current financial position. The movement on the allowance for doubtful debts on trade receivables and other receivables is as follows:

	31 December 2015 £'000	31 December 2014 £'000
Balance at beginning of the year	—	—
Impairment losses recognised through the consolidated statement of comprehensive income for the year	—	—
Amounts written off as unrecoverable during the year	—	—
Balance at end of the year	—	—

As at 31 December 2015 trade and other receivables of £3,000 (2014: £280,000) were past due but not impaired. The age profile of these balances is as follows:

	31 December 2015 £'000	31 December 2014 £'000
Up to three months	3	279
Three to six months	—	1
	3	280

The Directors believe that the carrying value of trade and other receivables represents its fair value. All trade receivables are denominated in pounds Sterling (£). In determining the recoverability of trade receivables the Group considers any change in the credit quality of the receivable from the date credit was granted up to the reporting date.

For details on the Group's credit risk management policies, refer to note 25.

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

20. Short-term deposits

	31 December 2015 £'000	31 December 2014 £'000
Short-term deposits	37,031	28,007

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

21. Cash and cash equivalents

	31 December 2015 £'000	31 December 2014 £'000
Cash at bank and in hand	14,205	22,826

All the Group's cash and cash equivalents at 31 December 2015 and 31 December 2014 are at floating interest rates. Included in the cash and cash equivalents of the Group at 31 December 2015 was the equivalent of £70,000 (31 December 2014: £204,000) denominated in US Dollars and £5,000 denominated in Euros (31 December 2014: £100,000); the remaining cash and cash equivalents balance was denominated in pounds Sterling (£).

The Directors consider that the carrying value of cash and cash equivalents approximates fair value. For details on the Group's credit risk management, refer to note 25.

22. Trade and other payables

	31 December 2015 £'000	31 December 2014 £'000
Trade payables	2,265	2,754
Other taxes and social security	382	414
VAT Payable	984	—
Other payables	5,134	177
Accruals	1,303	903
Deferred income	7,434	370
	17,502	4,618

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

The Directors consider that the carrying value of trade and other payables approximates fair value. Included within trade payables of the Group as at 31 December 2015 was the equivalent of £173,000 (31 December 2014: £nil) denominated in US Dollars. The remaining trade and other payables are denominated in pounds Sterling (£).

Other payables include deferred consideration of £5.0 million in respect of the equity investment in PrEP Biopharm Limited which was paid in January 2016 (see note 29).

Deferred income includes £6.4 million in respect of licencing arrangements with PrEP Biopharm Limited (see note 29).

The Group has financial risk management policies in place to ensure that trade payables are settled within the credit timeframe and no interest has been charged by any suppliers as a result of late payment of invoices during the reporting periods presented herein. (see note 25)

23. Other payables

	31 December 2015 £'000	31 December 2014 £'000
Amounts to be settled beyond one year	475	550

On 11 March 2013, the Group signed an Agreement for Lease with Queen Mary BioEnterprises Limited to develop the 3rd 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 3rd floor, with £75,000 per annum repayable over a ten-year period. The lease incentive is recognised as a liability. In the event 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.

Notes to the consolidated financial statements continued

24. Provisions

	31 December 2015 £'000	31 December 2014 £'000
Dilapidations provision	140	130
Onerous lease provision	3,000	3,000
	3,140	3,130

	Onerous lease provision £'000	Dilapidations provision £'000	Total £'000
At 1 January 2015	3,000	130	3,130
Additional provision in the year	993	10	1,003
Used during the year	(993)	—	(993)
At 31 December 2015	3,000	140	3,140

Onerous lease provision of £3.0 million (31 December 2014: £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 2016 and 2018. Total expected costs to be incurred are £3.0 million.

Buildings dilapidations of £140,000 (31 December 2014: £130,000) 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.

25. Financial risk management

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

Capital management

The Group manages its capital to ensure that it will be able to continue as a going concern while maximising the return to stakeholders. The Group is funded principally by equity although long-term and short-term loans have been utilised from time to time. As at 31 December 2015, a repayable lease incentive of £550,000 was outstanding (31 December 2014: £625,000).

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

Financial assets

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

	31 December 2015 £'000	31 December 2014 £'000
Cash and cash equivalents	14,205	22,826
Short-term deposits	37,031	28,007
Trade receivables	551	446
Other receivables	405	667
Accrued income	412	162
	52,604	52,108

Financial liabilities

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

	31 December 2015 £'000	31 December 2014 £'000
Trade payables	2,265	2,754
Accruals	1,303	903
Repayable lease incentive from related parties	550	625
Other payables	5,059	177
	9,177	4,459

Market risk

The Group's activities expose it primarily to the financial risks of changes in foreign currency exchange rates and interest rates. In the year ending 31 December 2015, both these risks are considered to have been minimal.

Credit risk

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

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

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

There were no other significant concentrations of credit risk at the reporting date. At 31 December 2015, the Group's trade receivables balance was £551,000 (31 December 2014: £446,000).

The carrying amount of financial assets recorded in the Financial Statements, net of any allowances for losses, represents the Group's maximum exposure to credit risk. At 31 December 2015, the allowance for impairment losses totalled £nil (31 December 2014: £nil). In the opinion of the Directors, there has been £nil impairment of financial assets during the year ended 31 December 2015 (31 December 2014: £nil).

An allowance for impairment is made where there is an identified loss event which, based on previous experience, is evidence of a reduction in the recoverability of the cash flows. Management considers the above measures to be sufficient to control the credit risk exposure.

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

Liquidity risk management

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

At 31 December 2015, the Group had short-term deposits, and cash and cash equivalents of £51.2 million (31 December 2014: £50.8 million).

Foreign currency risk management

Historically, the Group's exposure to foreign currency risk has been limited, as all of its invoicing and the majority of its payments are in Pounds Sterling. However, increased US Dollar expenditure with US suppliers and higher employee headcount of hVIVO Inc resulted in a Group cash outflow of \$2.9 million US Dollars during 2015. Foreign exchange risk is managed through the purchase of US Dollars throughout the year.

The balance held in foreign currencies at the end of the reporting period was not material and the Group has made no payments in foreign currencies other than US Dollars and Euros. As such, management has not presented any sensitivity analysis in this area as this is immaterial.

Maturity of financial assets and liabilities

With the exception of the lease incentive from a related party (see note 23), all of the Group's non-derivative financial liabilities and its financial assets at 31 December 2015 are either payable or receivable within one year.

Notes to the consolidated financial statements continued

26. Share capital

	Number	£'000
Issued and fully paid:		
At 1 January 2014	53,726,920	2,686
Issue of new ordinary shares – 3 March 2014	996,901	50
Issued under placing agreement – 1 September 2014	12,923,077	647
Issued pursuant to purchase by Non-Executive Directors – 5 November 2014	5,423	—
At 31 December 2014	67,652,321	3,383
Issued pursuant to purchase by Non-Executive Directors – 9 January 2015	7,122	—
Issue of new ordinary shares – 4 March 2015	438,072	22
Issued pursuant to purchase by Non-Executive Directors – 8 April 2015	7,231	—
Employee share option exercise – 13 May 2015	716,871	36
Employee share option exercise – 26 June 2015	108,604	5
Issued pursuant to purchase by Non-Executive Directors – 6 July 2015	5,426	—
Issued pursuant to purchase by Non-Executive Directors – 5 October 2015	6,026	1
Issue under placing agreement – 15 December 2015	9,111,111	456
At 31 December 2015	78,052,784	3,903

On 5 January 2016, 7,520 ordinary shares were allotted pursuant to the quarterly purchase of shares by Jaime Ellertson (Chairman of the Company) and James Winschel (Non-Executive Director) under the terms of their letters of appointment.

Options

Share options outstanding at 31 December 2015 have the following expiry date and exercise prices:

Grant date	Number ('000)	Option price (pence)	Date from which exercisable	Expiry date
7 April 2009	101	5.0	7 April 2010	6 April 2019
7 April 2009	101	5.0	7 April 2011	6 April 2019
7 April 2009	102	5.0	7 April 2012	6 April 2019
14 September 2009	53	6.3	14 September 2010	13 September 2019
14 September 2009	53	6.3	14 September 2012	13 September 2019
14 September 2009	54	6.3	3 May 2012	13 September 2019
13 January 2010	48	6.3	13 January 2011	12 January 2020
13 January 2010	49	6.3	13 January 2012	12 January 2020
13 January 2010	49	6.3	3 May 2012	12 January 2020
23 December 2011	792	8.2	3 May 2012	22 December 2021
23 December 2011	799	8.2	23 December 2012	22 December 2021
23 December 2011	805	8.2	23 December 2013	22 December 2021
3 March 2014	63	101.6	3 March 2014	18 December 2022
21 April 2015	502	337.3	21 April 2018	20 April 2025
	3,571			

Details of share options are disclosed in note 27 to the Financial Statements.

Components of equity

The components of equity are as follows:

- share capital and the share premium account, both of which arise on the issue of shares;
- share-based payment reserve, which results from the Company's grant of equity-settled share options to selected employees and Directors;
- merger reserve, which was created as a result of the acquisition by the Company of the entire issued share capital of hVIVO Services Limited in 2012 (see note 1). This reserve is not considered to be distributable;
- other reserve, which relates to unexercised share options issued in respect of the acquisition of Activiomics Limited in 2014; and
- retained deficit, which reflects losses incurred to date.

27. Share-based payments

hVIVO plc share option plans

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

On 21 April 2015 hVIVO implemented a new share scheme available to Executive Directors and key management. hVIVO granted 507,890 options over ordinary shares of 5.0 pence each in the Company to Directors and employees with an exercise price of £3.37 per share under a new share option plan.

Options are exercisable at a price equal to the estimated value of the Company's shares on the date of the grant. The options are settled in equity once exercised. If the options remain unexercised for a period after ten years from the date of grant, the options expire. Options are forfeited if the employee leaves the Group before the options vest.

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

	31 December 2015		31 December 2014	
	Number (‘000)	WAEP £	Number (‘000)	WAEP £
Outstanding at the beginning of the year	3,832	0.08	3,858	0.08
Expired during the year	(6)	3.37	(26)	0.08
Exercised during the year	(826)	0.08		
Granted during the year	508	3.37		
Outstanding at the end of the year	3,508	0.55	3,832	0.08
Exercisable at year end	3,006	0.08	3,832	0.08

The options outstanding at 31 December 2015 had a weighted average exercise price of £0.55 and a weighted average remaining contractual life of 6.0 years.

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

The Group recognised a charge of £78,000 (31 December 2014: £10,000) related to equity-settled share-based payment transactions during the year.

Acquisition of Activiomics

Under the terms of the agreement to purchase 100% of the ordinary shares of Activiomics Limited in 2014, the options of Activiomics Limited were exchanged for options on 69,229 shares in the Company on a like for like basis. As at 31 December 2015, 62,735 of the share options were fully vested and unexercised.

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

	31 December 2015		31 December 2014	
	Number (‘000)	WAEP £	Number (‘000)	WAEP £
Outstanding at the beginning of the year	69	1.02	—	—
Expired during the year	(6)	1.02	—	—
Exercised during the year	—	—	—	—
Granted during the year	—	—	69	1.02
Outstanding at the end of the year	63	1.02	69	1.02
Exercisable at year end	63	1.02	69	1.02

Adviser warrants

In part settlement of adviser fees in the year ending 31 December 2012, warrants over 204,885 ordinary shares were granted at an exercise price of 80 pence per ordinary share. On 4 March 2015, 204,885 ordinary shares were issued following the exercise of these warrants.

Notes to the consolidated financial statements continued

28. Pensions

The Group operates a defined contribution pension scheme whose assets are held separately from those of the Group in an independently administered fund. The pension charge represents contributions payable by the Group and amounted to £541,000 for the year (31 December 2014: £485,000). Contributions totalling £43,000 were payable to the fund at the year end and are included within trade and other payables (31 December 2014: £95,000).

29. Related party transactions

Remuneration of key personnel

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

	Year ended 31 December 2015 £'000	Year ended 31 December 2014 £'000
Executive Directors – aggregate		
Short-term employee benefits and fees	595	383
Employer's National Insurance contributions	81	70
Post-employment benefits	37	28
Share-based compensation charge	31	6
	744	487
Non-Executive Directors – aggregate		
Short-term employee benefits and fees	242	130
Payments to third parties	—	11
Total short-term employee benefits and fees	242	141
Total Directors' remuneration	986	628

Remuneration and benefits paid to the highest paid Director totalled £327,000 (31 December 2014: £226,000).

Amounts outstanding to key personnel

As at 31 December 2015, £3,000 was due in relation to employer pension contributions (31 December 2014: £46,000).

Transactions with the Group related parties

On 1 November 2015 the Company acquired a significant stake in the equity of PrEP Biopharm Limited for consideration of £14.0 million. As at 31 December 2015 £5.0 million of the Group's investment in PrEP Biopharm Limited was deferred consideration, which was paid in January 2016. PrEP Biopharm Limited contracted with hVIVO Services Limited on an arm's length basis for the delivery of hVIVO owned intellectual property in flu and asthma under licencing arrangements and also to conduct a Phase II durability study for a total consideration of £10.0 million. During the year £200,000 was recognised as revenue in relation to this programme of work. As at 31 December 2015 all amounts invoiced and due from PrEP Biopharm Limited to hVIVO in respect of flu and asthma licence arrangements and the Phase II durability study were fully paid.

During 2015, the Group entered into a three year contract with Everbridge Europe Limited for the provision of communication services payable in three fixed annual payments of £85,000 per annum. Everbridge Europe Limited is a subsidiary of Everbridge Inc, for whom Jaime Ellertson acts as Chairman and CEO. During the year £11,000 of costs were recognised by the Group in relation to the contract and as at 31 December 2015 Everbridge invoices of £102,000 were outstanding.

During 2015, The Group paid £1.3 million (gross) for rent and facilities (2014: £1.3 million (gross)) to Queen Mary, University of London ("QMUL"), a shareholder, and an entity related to QMUL, Queen Mary BioEnterprises Limited ("QMB"). At 31 December 2015 the Group had invoices of £317,000 (gross) (2014: 304,000 (gross)) outstanding and a repayable lease incentive of £550,000 (2014: £625,000)

30. Operating lease arrangements

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

	31 December 2015 £'000	31 December 2014 £'000
Within one year	2,056	1,510
In the second to fifth years inclusive	4,037	5,099
After five years	—	200
	6,093	6,809

The operating lease commitments include £3.5 million in respect of a lease which had been identified as being onerous at year end and accordingly, a provision has been made (see note 24).

31. Capital commitments

At the reporting date, the Group had no capital commitments (31 December 2014: £nil).

32. Note to the consolidated statement of cash flows

	2015 £'000	2014 £'000
Cash flow from operating activities		
Loss before income tax	(21,625)	(22,705)
Adjustments for:		
Share of loss of associate	146	—
Depreciation of property, plant and equipment	1,342	1,221
Impairment of property, plant and equipment	—	672
Amortisation of intangible assets	318	435
Payment of Non-Executive Director fees by issue of shares	68	15
Share-based payment expense	78	10
Finance costs	17	15
Finance income	(387)	(358)
(Gain)/loss on foreign exchange	(8)	8
Increase in provisions	10	3,020
Changes in working capital:		
Decrease/(increase) in inventories	1,590	(615)
Increase in current intangible asset	(2,935)	—
Increase in R&D Expenditure Credit asset	(352)	—
Decrease in trade and other receivables	249	2,965
Increase/(decrease) in trade and other payables	7,885	(3,835)
Cash used in operations	(13,604)	(19,152)
Finance costs	(17)	(15)
Income tax refund	3,775	2,568
Net cash used in operating activities	(9,846)	(16,599)

Trade and other payables include deferred consideration of £5.0 million in respect of the equity investment in PrEP Biopharm Limited which was paid in January 2016. This amount has not been included as a change in working capital as it relates to investing activities.

As at 31 December 2015, a £352,000 asset has been recognised in respect of an R&D Expenditure Credit ("RDEC"). 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.

Company statement of financial position

At 31 December 2015

	Note	2015 £'000	2014 £'000
Assets			
Non-current assets			
Investments in subsidiaries	3	19,781	19,703
Investments in associates	4	14,405	—
		34,186	19,703
Current assets			
Trade and other receivables	5	164	120
Amounts due from Group undertakings		37,335	23,611
Short-term deposits	6	37,031	28,007
Cash and cash equivalents	7	10,159	22,053
		84,689	73,791
Total assets		118,875	93,494
Equity and liabilities			
Equity			
Share capital	10	3,903	3,383
Share premium account		93,145	72,498
Share-based payment reserve		144	249
Merger reserve		16,530	16,530
Other reserve		211	921
Retained deficit		(457)	(281)
Total equity		113,476	93,300
Current liabilities			
Trade and other payables	8	5,399	194
Total liabilities		5,399	194
Total equity and liabilities		118,875	93,494

The Financial Statements of hVIVO plc (registered company number 08008725) on pages 64 to 70 were approved and authorised for issue by the Board on 19 April 2016 and signed on its behalf by:



Kym Denny
Chief Executive Officer



Graham Yeatman
Chief Financial & Business Officer

Company statement of changes of equity

for the year ended 31 December 2015

	Share capital £'000	Share premium account £'000	Share-based payment reserve £'000	Merger reserve £'000	Other reserve £'000	Retained deficit £'000	Total equity £'000
As at 31 December 2013	2,686	37,363	239	16,530	—	44	56,862
Proceeds from shares issued:							
Issue of new shares	—	15	—	—	—	—	15
Placing net of related expenses	647	32,133	—	—	—	—	32,780
Total transactions with owners in their capacity as owners	647	32,148	—	—	—	—	32,795
Loss for the year	—	—	—	—	—	(325)	(325)
Acquisition of subsidiary	50	2,987	—	—	921	—	3,958
Share-based payment expense	—	—	10	—	—	—	10
As at 31 December 2014	3,383	72,498	249	16,530	921	(281)	93,300
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	(183)	—	(710)	—	20,274
Loss for the year	—	—	—	—	—	(176)	(176)
Share-based payment expense	—	—	78	—	—	—	78
As at 31 December 2015	3,903	93,145	144	16,530	211	(457)	113,476

Company statement of cash flows

for the year ended 31 December 2015

	2015 £'000	2014 £'000
Cash flow from operating activities		
Loss before income tax	(176)	(325)
Adjustments for:		
Payment of Non-Executive Director fees by issue of shares	68	15
Finance income	(380)	(350)
Changes in working capital:		
Increase in trade and other receivables	(280)	(2)
Increase in trade and other payables	207	149
Cash used in operations	(561)	(513)
Net cash used in operations	(561)	(513)
Investing activities		
Loans to subsidiaries	(13,500)	(15,000)
Increase in balances on short-term deposits	(9,024)	(5,507)
Payment to acquire associate	(9,405)	
Payment to acquire subsidiary	—	(41)
Interest received	391	354
Net cash used in investing activities	(31,538)	(20,194)
Financing activities		
Net proceeds from issue of shares	20,205	32,780
Net cash generated from financing activities	20,205	32,780
Net (decrease)/increase in cash and cash equivalents	(11,894)	12,073
Cash and cash equivalents at the start of year	22,053	9,980
Cash and cash equivalents at the end of year	10,159	22,053

Notes to the Company financial statements

1. Principal accounting policies

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

The Financial Statements have been prepared on the historical cost basis. The principal accounting policies adopted are the same as those set out in note 2 of the Group's Financial Statements, except where noted below.

Investments

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

Share-based payments

Refer to note 2 of the Group's Financial Statements for the principal accounting policy relating to share-based payments.

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

2. Company results

The Company has taken the exemption under section 408 of the Companies Act 2006 not to present the Parent Company's income statement. The Parent Company's result for the period ended 31 December 2015 was a loss of £176,000 (2014: £325,000).

The audit fee for the Company is set out in note 7 of the Group's Financial Statements.

3. Interest in subsidiaries

	31 December 2015 £'000	31 December 2014 £'000
Investments in subsidiaries:		
Balance at beginning of year	19,703	17,707
Additions	—	4,000
Dividend in specie	—	(2,014)
Share-based compensation adjustment	78	10
Balance at end of year	19,781	19,703

Details of the Company's subsidiaries at 31 December 2015 are as follows:

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

On 20 April 2012 ownership of hVIVO Services Limited (formerly Retroscreen Virology Limited) was transferred to the Company in exchange for the issue of ordinary shares in the Company. The Company opted to hold its investment in its subsidiary companies at cost in accordance with IAS 27 Consolidated and Separate Financial Statements. As a consequence, the investment has been adjusted from the nominal value of the shares issued to the fair value of the shares issued in exchange for the shares acquired as a result of the business combination. A corresponding adjustment was made to equity by recognition of a merger reserve given the criteria for relief under section 131 of the Companies Act 1985 had been met at that time.

Notes to the Company financial statements continued

4. Interest in associates

2015
£'000

As at 1 January	—
Additions	14,405
As at 31 December	14,405

On 1 November 2015 the Company acquired 62.62% of the share capital of PrEP Biopharm Limited ("PrEP Biopharm") for cash consideration of £14.0 million, of which £5.0 million was deferred 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 is a UK based development stage biopharmaceutical company which is developing infectious disease products. At the same time as the investment, PrEP Biopharm entered into contractual arrangements with hVIVO Services Limited to the value of £10.0 million (see note 29).

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

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

Under the terms of the ISHA, hVIVO has appointed two of the current four Directors of PrEP Biopharm, including the Chair, with equal votes and no casting vote. Accordingly, hVIVO does not control the Board. In addition, it is anticipated that PrEP Biopharm will appoint an additional one or two Non-Executive Directors in the short term.

The terms of the ISHA exclude the hVIVO Directors from any Board consideration and decision making on the hVIVO contracts. Under the terms of the PrEP Biopharm transaction, PrEP Biopharm contracted with hVIVO Services Limited for the delivery of hVIVO owned intellectual property in flu and asthma under licencing arrangements and also to conduct a Phase II durability study for a total consideration of £10.0 million. The hVIVO contracts with PrEP Biopharm are priced on an arms-length basis and with normal terms.

hVIVO has concluded that despite having significant influence, the terms of the ISHA mean that it does not have the power to direct the relevant activities of PrEP Biopharm. Accordingly, hVIVO's investment in PrEP Biopharm has been accounted for as an investment in an associate.

5. Trade and other receivables

	31 December 2015 £'000	31 December 2014 £'000
Other receivables	54	—
Prepayments and accrued income	110	120
	164	120

6. Short-term deposits

	31 December 2015 £'000	31 December 2014 £'000
Short-term deposits	37,031	28,007

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

7. Cash and cash equivalents

	31 December 2015 £'000	31 December 2014 £'000
Cash at bank and in hand	10,159	22,053

All of the Group's cash and cash equivalents at 31 December 2015 are at floating interest rates and are all denominated in pounds Sterling (£).

The Directors consider that the carrying value of cash and cash equivalents approximates their fair value. For details on the Company's credit risk management, refer to note 25 to the Group's Financial Statements.

8. Trade and other payables

	31 December 2015 £'000	31 December 2014 £'000
Trade payables	268	94
Social security and other taxes	39	22
Accruals	92	76
Other payables	5,000	2
	5,399	194

Other payables include deferred consideration of £5.0 million in respect of the equity investment in PrEP Biopharm Limited which was paid in January 2016.

9. Financial instruments

Principal financial instruments

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

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

Financial assets

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

	31 December 2015 £'000	31 December 2014 £'000
Short-term deposits, cash and cash equivalents	47,190	50,060
Other receivables	111	117
	47,301	50,177

Financial liabilities

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

	31 December 2015 £'000	31 December 2014 £'000
Trade payables	268	94
Accruals	92	76
Other payables	5,000	2
	5,360	172

Refer to note 25 to the Group's Financial Statements for more information.

Notes to the Company financial statements continued

10. Share capital

Refer to note 26 to the Group's Financial Statements.

11. Share-based payments

Refer to note 27 to the Group's Financial Statements.

12. Related party transactions

Remuneration of key personnel

The remuneration of the Directors, who are the key management personnel of the Group, is shown at note 29 to the Group Financial Statements.

Transactions with the Group's shareholders

The amounts paid to shareholders and their connected parties (including VAT) were as follows:

	31 December 2015 £'000	31 December 2014 £'000
Non-Executive Director fees	—	13
Other expenses recharged	—	2
	—	15

No balances were outstanding to shareholders at the end of the year (2014: £nil).

Glossary

antiviral a drug effective against viruses which cause disease

attenuated virus reduction of the ability of a virus to induce disease (virulence)

biomarker a measurable substance that is indicative of a phenomenon, such as disease, infection or environmental exposure

challenge study utilises challenge agents, such as respiratory viruses, to elicit common self-limiting diseases such as flu, cold and RSV in human volunteers; subject is then given therapy or a placebo and monitored to measure response

clinical trial (or trial) a formal study of a therapeutic in order to demonstrate safety and efficacy and required in order to obtain regulatory approval of a therapeutic

COPD (chronic obstructive pulmonary disease) is a disease of the lungs in which the airways narrow over time, limiting airflow to and from the lungs, causing shortness of breath

efficacy the ability of a drug to produce a desired outcome or effect

endotype a subtype of a condition, such as asthma, which is defined by a distinct functional or pathobiological/disease mechanism

EU European Union

exacerbation an increase in the severity of a disease, its signs or its symptoms

FDA (Food and Drug Administration) the US government body responsible for the regulation of, testing and approval of therapeutics and medical devices in the US

field-based trials for cold and flu research, studies where volunteers already showing symptoms of cold or flu are recruited – often via a patient's presentation at a clinic, hospital or pharmacy

GCP (Good Clinical Practice) an international quality standard for clinical trials

H3N2 a subtype of influenza viruses that can infect birds and mammals. In birds, humans, and pigs, the virus has mutated into many strains and is increasingly abundant in seasonal influenza

host response defense mechanism of the host (human) against exogenous microorganisms such as viruses or human disease/injury

HRV (human rhinovirus) the group of viruses predominantly responsible for causing the common cold

human disease model controlled study to observe the entire disease lifecycle as subjects move from healthy to sick and recover back to healthy again; generates high-quality, longitudinal data from the before, during and after phases of disease. Can be used to study the efficacy of new therapies such as antiviral drugs and vaccines and also to study the target disease itself

IAS International Accounting Standards

IASB International Accounting Standards Board

IFRS International Financial Reporting Standards

influenza (or flu) a contagious virus infection that affects the respiratory system. Symptoms commence after an incubation period of one to four days and include headache, fever, loss of appetite and general aches and pains. Influenza viruses are subject to a high degree of mutation, creating different strains

IP (intellectual property) patents, rights to inventions, utility models, copyright and related rights, trade marks, service marks, trade, business and domain names, rights in goodwill or to sue for passing off, unfair competition rights, rights in designs, rights in computer software, database right, rights in biological materials, rights in confidential information (including know-how and trade secrets) and any other intellectual property rights, in each case whether registered or unregistered and including all applications for and renewals or extensions of such rights, and all similar or equivalent rights or forms of protection in any part of the world

MHRA (Medicines and Healthcare Products Regulatory Authority) the UK government body responsible for the regulation of, testing and approval of therapeutics and medical devices in the UK

pathomics the term used to describe the identification of the physiological pathways that are activated or inactivated as a result of an insult to a specific point within a biological circuit

pathomics map describes the key biological pathways involved in the host (human) response to disease

pathway series of actions among molecules in a cell that leads to a certain product or a change in a cell

phenotype the set of observable characteristics of an individual or organism resulting from the interaction of its genetic makeup with the environment and/or presentation of disease

Phase I the phase of the approval process for a new therapeutic in which it is first given to healthy volunteers and tests carried out for safety and adverse effects

Phase II the phase of the approval process for a new therapeutic in which clinical trials are performed on larger groups to assess how well the therapeutic works, as well as to continue Phase I safety assessments in a larger group. Phase II studies may be divided into:

- **Phase IIa** intended primarily to investigate what is the most effective dose; and
- **Phase IIb** further work to investigate and demonstrate efficacy

Phase III the phase of the approval process for a new therapeutic that in Phase I and Phase II has been shown to be efficacious with tolerable side effects

PrEP Biopharm a private independent drug development company for respiratory infectious disease products

prophylactic a medicine or course of action used to prevent disease

protocol the detailed plan and description setting out how a clinical study is to be carried out

QMB Queen Mary BioEnterprises Innovation Centre, 42 New Road, London E1 2AX or, in a separate context, the landlord Queen Mary BioEnterprises Limited

quarantine the stage of a challenge study in which volunteers are screened for infection and studied within a residential unit under controlled conditions, quarantined from infectious contamination from the environment or from persons other than their fellow volunteers. A study under such quarantine conditions helps reduce interference from external factors such as drug and alcohol consumption, diet and environmental conditions which would otherwise exist in a field-based trial

reprofiling the repurposing or cultivation of new uses for existing drugs

RMP plan for identifying, assessing, responding to, monitoring and controlling, and reporting risks

RSV (respiratory syncytial virus) a type of virus which causes infections of the nose and throat and is a major cause of pneumonia in young children

sponsor a company or organisation which commissions hVIVO to carry out a clinical trial or related work on its behalf

therapeutic a drug used for treatment or cure of a disease – therapeutic may also refer to a drug with prophylactic effect, preventing or restricting the development of a disease

URVIs upper respiratory viral infections

vaccine a biological preparation that improves immunity to a particular disease

virology the study or science of viruses

virus an infective agent generally consisting of a nucleic acid molecule within a protein shell, only able to multiply within the cells of a host

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