

**Open Orphan plc**

---

**Investor Presentation  
June 2020**

# Disclaimer

---



- The contents of this presentation and the information which you are given at the time of the presentation have not been approved by an authorised person within the meaning of the Financial Services and Markets Act 2000 (the "Act"). Reliance on this presentation for the purpose of engaging in investment activity may expose an individual to a significant risk of losing all of the property or other assets invested. This presentation does not constitute or form part of any offer for sale or subscription or solicitation of any offer to buy or subscribe for any securities in Open Orphan plc (the "Company") nor shall it form the basis of or be relied on in connection with any contract or commitment whatsoever. No reliance may be placed for any purpose whatsoever on the information contained in this presentation and/or opinions therein. This presentation is exempt from the general restriction (in section 21 of the Act) on the communication of invitations or inducements to engage in investment activity on the grounds that it is made to: (a) persons who have professional experience in matters relating to investments who fall within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the "Order"); or (b) high net worth entities and other persons to whom it may otherwise lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "relevant persons"). Any person (whether a relevant person or otherwise) is recommended to seek their own independent financial advice from a person authorised for the purposes of the Act before engaging in any investment activity involving the Company's securities. Any recipient who is not a relevant person should return this presentation to the Company's registered office and should not act upon it. By accepting this presentation and not immediately returning it, each recipient warrants, represents, acknowledges and agrees that it is a relevant person.
- This presentation does not constitute or form part of any offer or invitation or inducement to sell, issue, purchase or subscribe for (or any solicitation of any offer to purchase or subscribe for) the Company's securities in the UK, US or any other jurisdiction and its distribution does not form the basis of, and should not be relied on in connection with, any contract or investment decision in relation thereto nor does it constitute a recommendation regarding the Company's securities by the Company or its advisers and agents. Nothing in the presentation shall form the basis of any contract or commitment whatsoever. The distribution of this presentation outside the UK may be restricted by law and therefore persons outside the UK into whose possession this presentation comes should inform themselves about and observe any such restrictions as to the distribution of this presentation. The Company has not registered, and does not intend to register, any securities under the US Securities Act of 1933, as amended or to conduct a public offering of any securities in the US.
- This presentation contains "forward-looking" statements, beliefs, estimates, forecasts and opinions, including statements with respect to the business, financial condition, results of operations and plans of the Company and its group ("Group"). These forward-looking statements involve known and unknown risks and uncertainties, many of which are beyond the Company's control and all of which are based on the current beliefs and expectations of the directors about future events. Recipients should note that past performance is not necessarily an indication of future performance and no assurance can be given that they will be attained. Forward-looking statements are sometimes identified by the use of forward-looking terminology such as "believes", "expects", "may", "will", "could", "should", "shall", "risk", "intends", "estimates", "aims", "plans", "predicts", "continues", "assumes", "positioned" or "anticipates" or the negative thereof, other variations thereon or comparable terminology or by discussions of strategy, plans, objectives, goals, future events or intentions. These forward-looking statements may and often do differ materially from actual results.
- The significant risks related to the Company's business which could cause the Company's actual results and developments to differ materially from those forward-looking statements are discussed in the Company's Annual Report and other filings. They appear in a number of places throughout this presentation and include statements regarding the intentions, beliefs or current expectations of the directors of the Company with respect to future events and are subject to risks relating to future events and other risks, uncertainties and assumptions relating to the Group's business, concerning, amongst other things, the results of operations, financial condition, prospects, growth and strategies of the Group and the industry in which it operates. No one will publicly update or revise any forward-looking statements or any other information contained herein, either as a result of new information, future events or otherwise.
- In considering the performance information contained herein, recipients should bear in mind that past performance is not necessarily indicative of future results, and there can be no assurance unrealised return projections will be met. Certain of the past performance information presented herein may not be representative of all transactions of a given type. Actual events could differ materially from those projected herein and depend on a number of factors, including the success of the Group's development strategies, the successful and timely completion of clinical studies, securing satisfactory licensing agreements for products, the ability of the Group to obtain additional financing for its operations and the market conditions affecting the availability and terms of such finances.
- The Company reports under IFRS. Where foreign currency equivalents have been provided for convenience in this presentation, the exchange rates applied are those used in the relevant financial statements from which the figures have been extracted. This presentation is confidential and is being supplied to each recipient of it solely for its information. While this presentation has been prepared in good faith, no representation, warranty, assurance or undertaking (express or implied) is or will be made, and no responsibility or liability is or will be accepted by the Company or by its officers, employees or agents in relation to the adequacy, accuracy, completeness or reasonableness of this presentation, or of any other information (whether written or oral), notice or document supplied or otherwise made available to any recipient. This presentation has been prepared to assist a recipient make its own evaluations and does not purport to be all-inclusive or contain all of the information a recipient may desire.

# Experienced management with strong operational track record



## KEY MANAGEMENT



**Cathal Friel**  
Executive Chairman

- Established Raglan Capital in 2007 and co-founded Open Orphan in 2016
- Co-founder and remains significant shareholder in Amryt Pharma plc, a leading publicly listed orphan drug company
- Founder and Chairman of Fastnet Oil & Gas plc which listed in 2012 and raised \$50m in equity on the AIM market



**Tim Sharpington**  
Chief Operating Officer

- More than 25 years experience in the life sciences sector with various pharma, biotech and pharma service companies in Europe and the US
- Has broad experience in drug development, product licensing, M&A, and fundraising
- Previous positions at Pfizer, ICON, Sequus Inc, Arakis, Vectura and NED at Ixico PLC



**Leo Toole**  
Chief Financial Officer

- Over 20 years' experience in senior finance roles in Pharmaceuticals, Medical Technology and FMCG sectors.
- Extensive experience in building finance teams, corporate development, equity and debt financing, public markets, and mergers and acquisitions.
- He has held senior finance positions at Procter and Gamble, ResMed and Sublimity Therapeutics.



**Andrew Catchpole**  
Chief Scientist

- Approximately 20 years' experience in virus research and the application of scientific concepts within a commercial setting
- Experienced scientific strategy and operational delivery leader
- Viral Challenge Model expert with over 14 years advising pharma and biotech on vaccine and antiviral efficacy testing
- Has extensive involvement in the entire business development process



## NON-EXEC. DIRECTORS



**Michael Meade** Non-Executive Director

- Spent the last 30 years working in investment banking in London with HSBC, UBS and Numis Securities respectively
- Specialised in advising small and mid-cap quoted companies with particular focus on healthcare sector



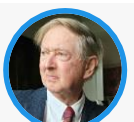
**Mark Warne** Non-Executive Director

- Has served as NED on the hVIVO Board since April 2016 and is a NED of Ixico Plc
- CEO of DeepMatter Group since 2018, and spent the previous 10 years at IP Group, leading the healthcare team and serving as partner



**Prof Brendan Buckley** Non-Executive Director

- Chief Medical Officer of ICON Plc from 2013-2017, and was as a member of ICON plc's Executive Leadership Team being actively involved in M&A
- Sold his previous business Firecrest Clinical to ICON Plc and has over 30 years' experience in clinical research



**Prof John Oxford** Chairperson of Scientific Advisory Board

- Professor of Virology at St Bartholomew's and the Royal London Hospital, Queen Mary's School of Medicine and Dentistry
- Founder of Retroscreen Virology now known as hVIVO, a leader in the field of vaccine and anti-viral clinical trials for the last 20 years



# Key attributes

---



Open Orphan  
is now a niche  
CRO business

Growing and  
expect to be  
profitable soon

High margin  
pharma service  
offering

Broad  
customer base  
which includes  
global pharma

Several new  
revenue  
streams  
started

Substantial and  
rapidly growing  
pipeline

# Business Overview



## Existing complementary CRO Services, profitable H2

### hVIVO services



**Unique cashflow positive CRO with large upfront cash payment on signing and regular milestone payments**

- The world leader in the testing of vaccines, antivirals, and respiratory disease medications
- Run from its 24-bedroom quarantine clinic in East London (c. £25m), with an onsite virology laboratory (c. £10m)
- World leading portfolio of 8 challenge studies: 2 Flu, 2 RSV, 1 HRV, 1 Asthma, 1 Cough, and 1 COPD (replacement cost c. £25m)
- Developing the world's first seasonal Coronavirus, and Covid-19, challenge studies

### Venn services



**Venn Life Sciences**

- Drug development consultancy business
- Offers CMC, preclinical, PK and medical writing from its Dutch office
- Paris office being slimmed down, now offering Data Management Services, Biostatistics, and Randomisation
- Over 25 years servicing pharma companies



# Open Orphan plc Investor Information



## Investor Information

- Listed on the AIM market, London Stock Exchange and Euronext, Dublin Stock Exchange.
  - Ticker: ORPH
- Shares in issue: 22 June 2020: c. 664m
- Market Cap: 22 June 2020: £77.8m
- Cash Balance: 22 June 2020: £15.5m
- Debt: 22 June 2020: £1.4m
- Revenue last year: £24.3m
- Gross profit last year: £3.8m
- Normalized EBITDA last year: (£9.1m)
- Annualized cost savings
  - Implemented in 2019 £3.4m
  - Implemented already by May 2020 £4.5m
  - To be implemented by Dec 2020 £2.2m

£10.1m

## Open Orphan plc

- Offices in London, Paris, and Breda, Netherlands
- Open Orphan completed its IPO on the Dublin and London Stock Exchanges in June 2019 via the reverse takeover of Venn Life Sciences plc raising £4.5m at 5.6p.
- In January 2020 Open Orphan acquired hVIVO plc for £13m in an all equity acquisition and raised £5.3m in fresh equity at 6.1p.
- June 2020 Open Orphan completed fundraise of £12m

## Larger Shareholders

- Cathal Friel and Co-Founders c. 20%
- Invesco 7.91%

# Progress since merger on the 17<sup>th</sup> January



## *What we said we'd do*

- Integrate the businesses, reduce cost base, expand hVIVO's laboratory services, convert the hVIVO pipeline of contracts, and get profitable

## *What we've done*

- Completed the above and removed €2m from hVIVO cost base, €3m from Venn cost base, and a further €2.5m reduction by December 2020
- Expect to be operationally profitable by Q3, right-size management team, combined CEO & other senior roles



### ***6th of March***

£3.2m pilot RSV study signed with a European biotech with a £7m pivotal study to follow later in 2020



### ***9th of March***

Launch of the world's first Coronavirus challenge study model



### ***23rd of April***

Expanding 3<sup>rd</sup> party lab services, contract signed with Nearmedic International



### ***4th of May***

£3.5m RSV study signed with North American biotech



### ***11th of May***

Transformational Covid-19 antibody testing business launched



# Challenge Study Business

## Our existing business

Challenge study models can potentially speed up vaccine development and approval by 2-3 years by testing the efficacy on human volunteers over a short period of time in a quarantine clinic

World leading portfolio of challenge study models – inc. flu, RSV, asthma, HRV, COPD, cough; replacement cost in excess of £25m

## The Covid-19 opportunity

- Currently c.100 Covid-19 vaccines in development around the world, in dialogue with 12 of the leading vaccine developers
- hVIVO 24 bed quarantine clinic, replacement cost c. £25m
  - can be made into 3 zones of 8 beds each so as to run 3 different vaccine company's studies at the same time
- The average study takes 2-4 months in clinic time
- There is a possibility we could sign 6 Covid studies this year and a further 6 next year
- Unprecedented growth opportunity as pharma focuses funding on Covid-19 and respiratory diseases

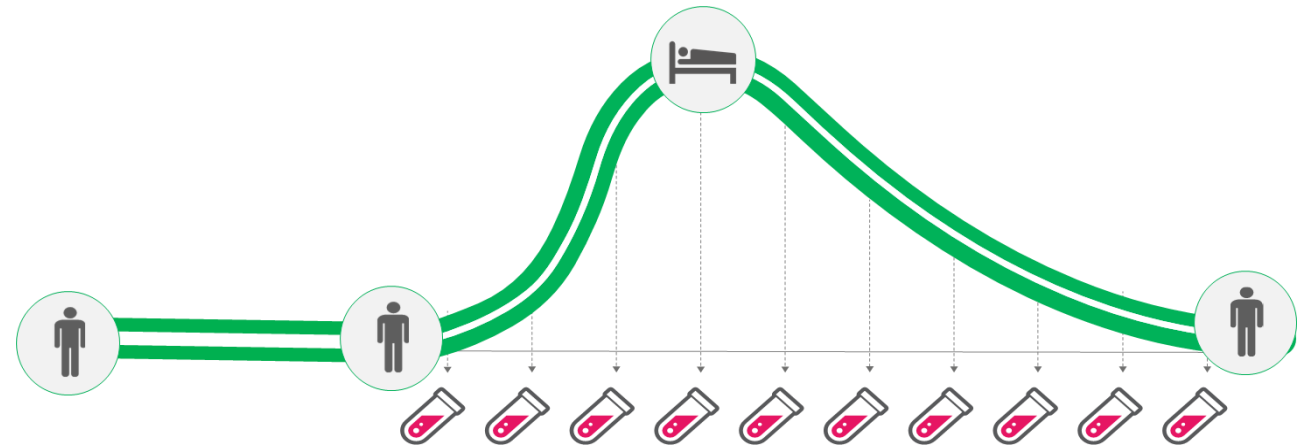




# Coronavirus challenge model – opportunity and rationale

## Vaccine developer's perspective

- Huge urgency around the world to demonstrate Covid-19 vaccines' effectiveness quickly
- Conventional vaccine trials in the field are expensive, take many months / years and require 1000's subjects
- Conventional trials require subjects to be exposed to virus in the community to be able to test vaccine - countries with successful Covid containment measures now have very low infection rates making vaccine trials near impossible (e.g., China)
- Pandemic likely to proceed in waves of higher and lower infection rates making vaccine testing timelines unpredictable
- Challenge models involve direct experimental infection of vaccinated subjects so all subjects exposed to disease – outcome is predictable, fast clinical study timelines
- Potential for emergency vaccine licensure utilising successful challenge study data



Graph above shows progression of a volunteer while in our clinic during a typical 2 week trial

**6<sup>th</sup> May WHO back use of challenge studies to speed up Covid vaccine approvals**

## Commercial Opportunity

- Immediate and growing customer demand for Covid 19-like challenge models to test Covid 19-specific vaccines & study Covid disease
- Currently no Covid-like challenge models available anywhere in the world
- Seasonal coronavirus model uses lower disease severity viruses (not Covid 19-like): utility now for antiviral testing and next phase of vaccines with universal coronavirus properties

# hVIVO lab services and testing capability



Post-merger we started selling lab services to third party pharma / biotech co.'s i.e. Nearmedic 23<sup>rd</sup> April

In the past hVIVO mainly serviced its internal lab



Huge opportunity to help UK increase its national lab testing capability; we lag Germany



Lab services could easily deliver £5m-£10m in annual revenues



Monday 11<sup>th</sup> May Open Orphan agreed deal with Quotient to commence up to 3,000 Covid-19 antibody tests per day

Potential to deliver tens of millions in annual testing revenue



Currently the only commercial lab in the UK to be able to provide the best-in-class Quotient Antibody testing platform, which has a 100% accuracy and 99.8% specificity



£10m replacement cost for the laboratory

# Open Orphan Genomic Health Data Platform to now include hVIVO's extensive infectious disease data



## hVIVO's infectious disease database

- Over the last 20 years hVIVO has built up a very extensive and valuable database of infectious disease progression etc
- Previously hVIVO never monetised its extensive disease database
- Discussions initiated with big pharma on collaborative deal involving access to infectious disease database, combined with fees-for-service clinical sample analysis to further expand the database, to aid identification or early infection biomarkers for antiviral development
- Access to this database will be made available to pharma companies late 2020 on an annual subscription basis

## Genomic Health Data Platform

- Platform build completed early 2020
- Early adopter pharma companies signed up
- Early adopter patient advocacy groups signed up
- Assists pharma companies in their drug discovery process
- Access to this data will be made available to pharma companies late 2020 on an annual subscription basis



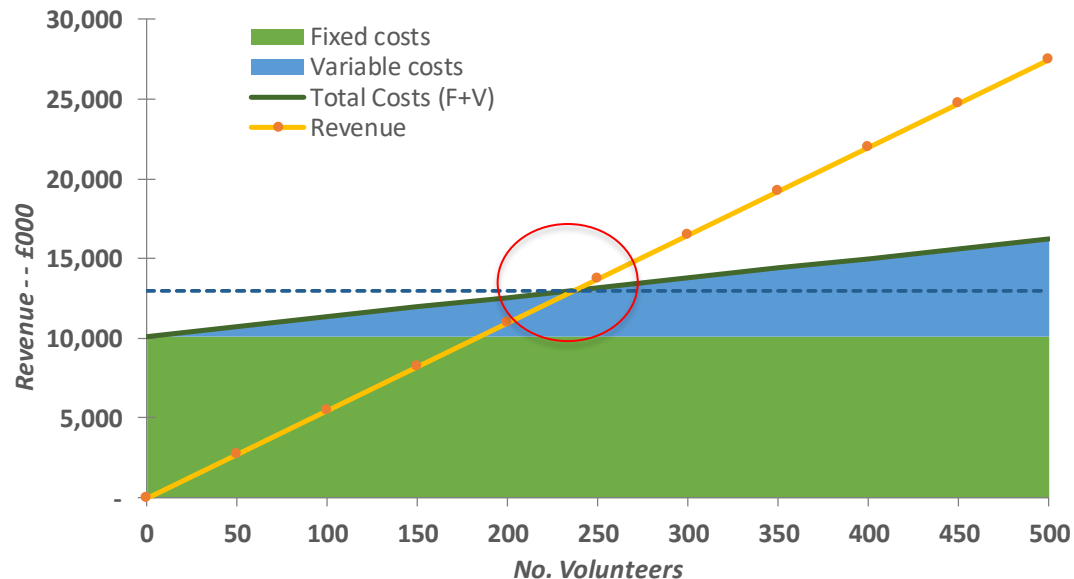
# Significant operational leverage – hVIVO



## Illustrative breakeven analysis of challenge study and laboratory services

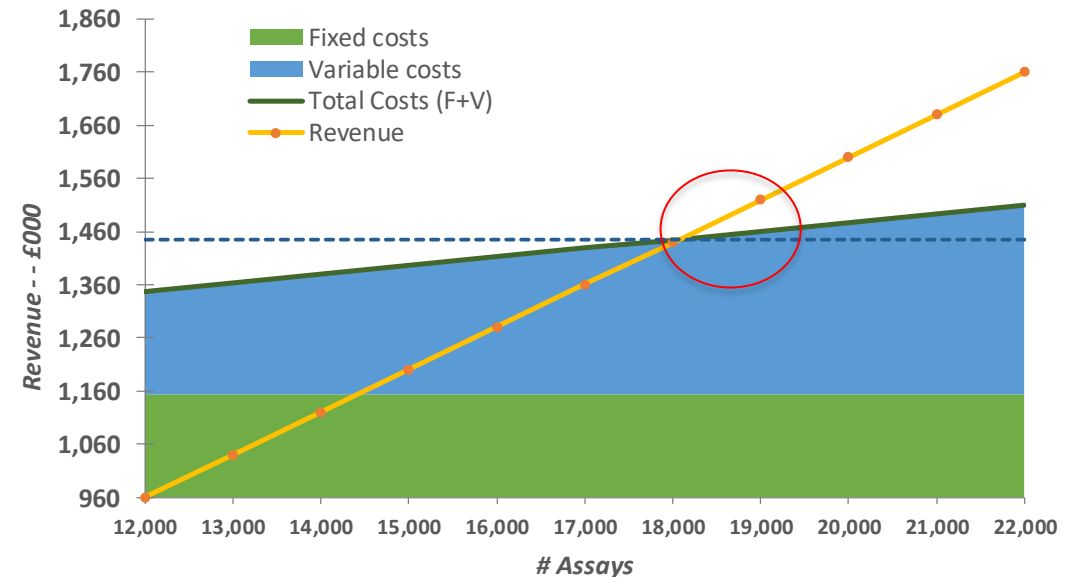
Estimated EBIT break-even point for challenge study clinic of ~£13m revenue i.e. 3 – 4 typically-sized studies and a unit utilisation rate of ~45%

### Challenge study clinic break-even



Estimated EBIT break-even point for laboratory services of ~£1.5m revenue i.e. ~ 18,000 assays/year depending on price/mix, a utilisation of <20%

### Laboratory services break-even



# Current trading and new customer wins



hVIVO strong pipeline results to build H2 2020 revenue forecast and to build momentum for 2021



hVIVO recent contract wins: 6<sup>th</sup> of March £3.2m RSV study, with £7m follow-on study, 4<sup>th</sup> of May £3.5m RSV study



Venn trading in line with last year despite Covid risks while managing cost reduction and office closures



Venn Q1 2020 €2.5m in recent contract wins with tier-1 pharma

# Prospect pipeline expanded with Covid-19 opportunities



## Pre-Covid

Existing combined pipeline of near term target contracts for hVIVO and Venn c. **£110m**

hVIVO pipeline c. **£100m** (>20% increase since January)

Venn pipeline c. **£10m**

## Post-Covid

Existing combined pipeline of near term target contracts for hVIVO and Venn c. **£110m**

Substantial new pipeline of opportunities to develop Covid challenges studies **£35m-£70m**

Third party pharma Covid laboratory testing opportunities **£5m-£10m**

Rollout of Covid antibody testing **£10m-£30m** with further upside potential

**Prospect pipeline is now in excess of £160m**

# Increased global awareness of our capability



- Following the March 9th launch of our Coronavirus challenge study, huge global interest, with 264 media companies and 185 TV and radio stations mentioning, and many seeking permission to film, our activities
- Exponential increase in our BD pipeline from vaccine companies around the world
- In active discussions with 12 of the leading Covid vaccine developers around the world
- Media coverage resulted in almost 50,000 volunteers registering on [www.flucamp.com](http://www.flucamp.com) - a huge asset

  
**THE SUNDAY TIMES**  
**Coronavirus vaccine race:  
volunteers to be infected in the  
UK**  
Human guinea pigs in a London lab are to be given a form of the killer virus as the search for a lucrative jab heats up

**BBC**

**CBS**

**RTL**

  
**NBC**

**Daily Mail**

**THE Sun**

**THE WALL STREET JOURNAL.**  
BUSINESS | HEALTH CARE | HEALTH  
**Wanted: People Willing to Get Sick  
to Find Coronavirus Vaccine**  
British lab is recruiting volunteers for study it says could speed development of Covid-19 vaccine



- ✓ Niche CRO business, growing and expect to be profitable soon
- ✓ High margin pharma services offering
- ✓ Broad customer base which includes global pharma
- ✓ Unprecedented growth opportunities as pharma focuses funding on Covid-19 and respiratory diseases
- ✓ Lab services poised to capitalise on Covid antibody testing

# Recent Shareholder Movements and building liquidity



Co-Founders

c. 19%,  
36 month  
lock-up  
since June 2019 IPO



Invesco **7.91%**

Post-merger, share register  
stabilised

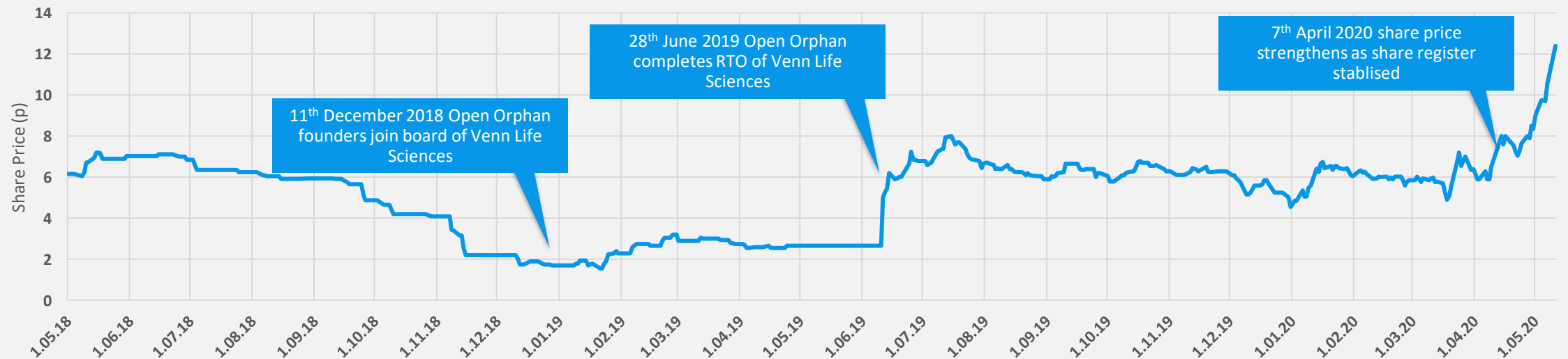
Share price has strengthened  
since removal of overhang  
in the past month



**May 2020 Fundraise**  
Heavily oversubscribed  
institutional  
placing



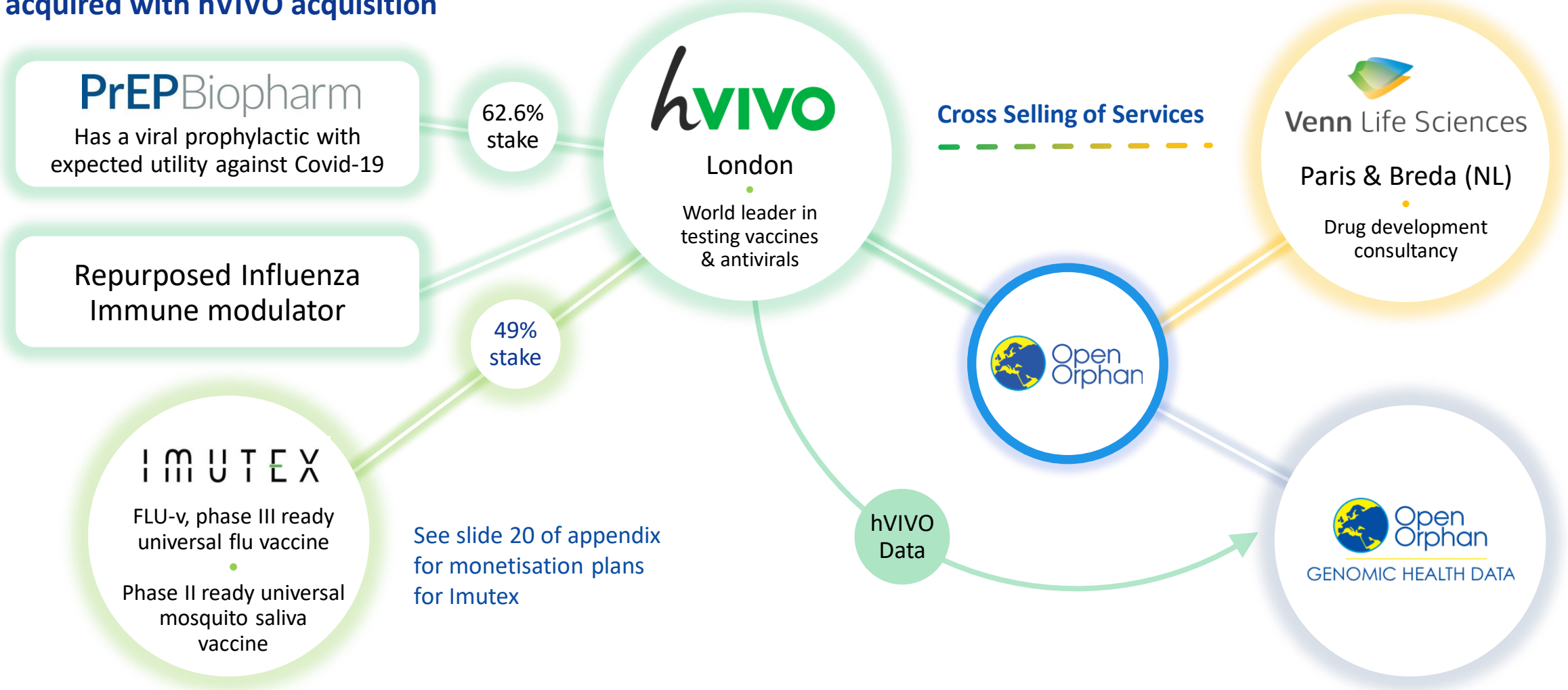
Open Orphan Share Price



# Open Orphan plc, a specialist CRO, with a number of non-core product assets



## Non-core product portfolio acquired with hVIVO acquisition



## Appendix – Additional information

# Monetising the non-core vaccine product portfolio acquired with the hVIVO acquisition



## Imutex Ltd, 49% owned by Open Orphan, 51% owned by Seek Group

- Strategic plan underway and subject to agreement by the SEEK Group could include:
  - sale of the asset for cash
  - bend it into a separate company with dividend specie payable to all Open Orphan shareholders
- Funding of this vaccine portfolio to be funded by out licensing deals with big pharma
- In recent months substantial increase in interest in universal flu vaccines and universal mosquito vaccines
- FLU-v, a phase III ready universal influenza vaccine candidate
- AGS-v, a phase II ready mosquito saliva vaccine, zika, malaria, and dengue etc
- Flu-v could be repurposed as a universal Covid vaccine



IMUTEX

## PrEPBiopharm Inc (USA), 62.6% owned by Open Orphan

- has a viral prophylactic with expected utility against Covid-19

PrEPBiopharm

## Immune modulator, 100% owned by Open Orphan

- In-licensed repurposed drug, with supporting patent applications
- Phase III ready immune modulator for severe influenza
- Team investigating potential Covid-19 applications

Immune Modulator

- ▲ Potential to bundle 100% of the above assets into a new public vehicle to create an exciting vaccine development company
  - Public markets, particularly Nasdaq, is ripe for such a topical company at the moment

# Human Viral Challenge Models

## What are Human Viral Challenge Models (also known as Controlled Human Infection Models or CHIMs):

- The Human Viral Challenge (HVC) model has, for many decades, helped in the understanding of respiratory viruses and their role in disease pathogenesis. In a controlled setting, using small numbers of volunteers removed from community exposure to other infections, volunteers are inoculated by known doses of the challenge virus and the disease time course monitored. All subjects are inoculated with virus but with some receiving a placebo and others the experimental drug to test the efficacy of the drug and obtain proof of concept data much quicker than can be achieved in the field. This experimental model enables proof of concept work to be undertaken on novel therapeutics, including vaccines, immunomodulators and antivirals, as well as new diagnostics.
- Crucially, unlike conventional phase 1 studies, challenge studies include invaluable efficacy endpoints that then guide decisions on how to optimise subsequent field studies, as recommended by the FDA, and thus licensing studies that follow. Such a strategy optimises the benefit of the studies and identifies possible threats early on, minimising the risk to subsequent volunteers, whilst also maximising the benefit of scarce resources available to the research group investing in the study. Inspired by the principles of the 3Rs (Replacement, Reduction and Refinement) now commonly applied in the preclinical phase, HVC studies allow refinement and reduction of the subsequent development phase, accelerating progress towards further statistically powered phase 2b studies. The breadth of data generated from challenge studies allows for exploration of a wide range of variables and endpoints that can then be taken through to pivotal phase 3 studies.

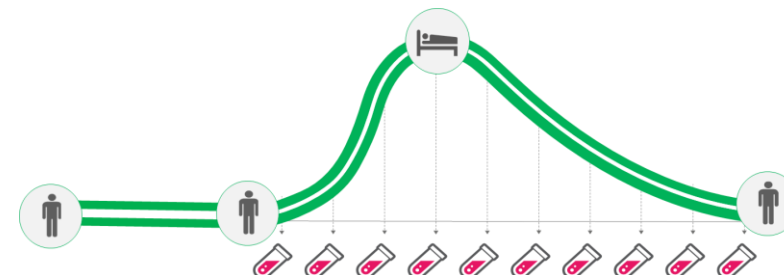
hVIVO today has a leading portfolio of 2 FLU, 2 RSV, 1 HRV, 1 Asthma, 1 cough, and 1 COPD viral challenge models  
To replicate this portfolio would likely cost in excess of £25m and take a minimum of 6 years work  
*No other challenge study service provider has such a comprehensive portfolio*

## World's first Coronavirus challenge model – Controlled human infection model

- In March 2020 hVIVO have initiated the development of a coronavirus challenge model
- Like our other challenge models, the model will involve recruiting healthy volunteers, inoculating them with coronavirus in quarantine, monitoring the disease and returning the subject to health
- This will aid in fast-tracking the testing of antiviral and vaccines against the coronavirus family
- The model will initially be developed using a common coronavirus strain from the same virus family, such as OC-43, that causes more mild symptoms
- Since the middle of April 2020 we are now also developing an attenuated Covid-19 virus challenge study model
- The model will also facilitate a greater understanding of the type and durability of the immune response coronavirus infections elicit
- Two phases are involved in the model development: Manufacture of the challenge virus and clinical testing to determine the appropriate viral dose to elicit the appropriate levels of disease.

The model is then ready for product testing

Graph below shows progression of a volunteer while in our quarantine clinic over a typical 2 week trial

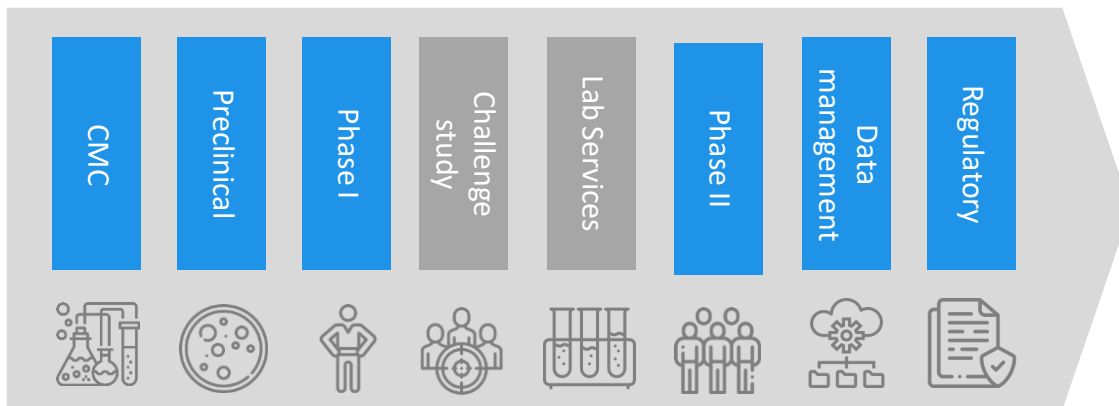


## Building a leading European rare/orphan disease focused pharma services company

### Overview

- Acquired AIM-listed Venn in June 2019 in RTO
- AIM & Euronext listed – ORPH
- Approx. 120 employees and dropping to less than 100 end Q1 2020, from 176 in January 2019
- Revenue: €14.3m in 2018
- Offices in Paris, Breda (Netherlands)
- Mgmt. own c. 19% under a 3 year lock-up from June 2019 IPO
- Over 400 studies completed in last 10 years, including 63 rare disease trials

### Current capabilities



### Turnaround / Strategy

- Venn IPO'd 2012, acquired Cardinal Systems in Paris 2014, and Kinesis Consulting in Netherlands in 2015, both established pharma consultancy companies for 25 years with deep relationships
- Substantial overhead reduction underway since RTO/IPO in June 2019 – reducing headcount from 176 to target of 80 end Q2 2020 (post-IPO we closed the Dublin, German, and second Dutch office), removing up to €3.85m from annualised cost basis with a view to being profitable in 2020
- Successfully moving Venn away from short-term contracts to long-term, 3-year contracts with recurring revenues, i.e. IPSEN (Nov '19), Carina Bioscience (Nov '19) German Tier One (Jan '20)
- Signed confirmed contracts of €10m for 2020, the highest in Venn's history

### Established Global customers and collaborations



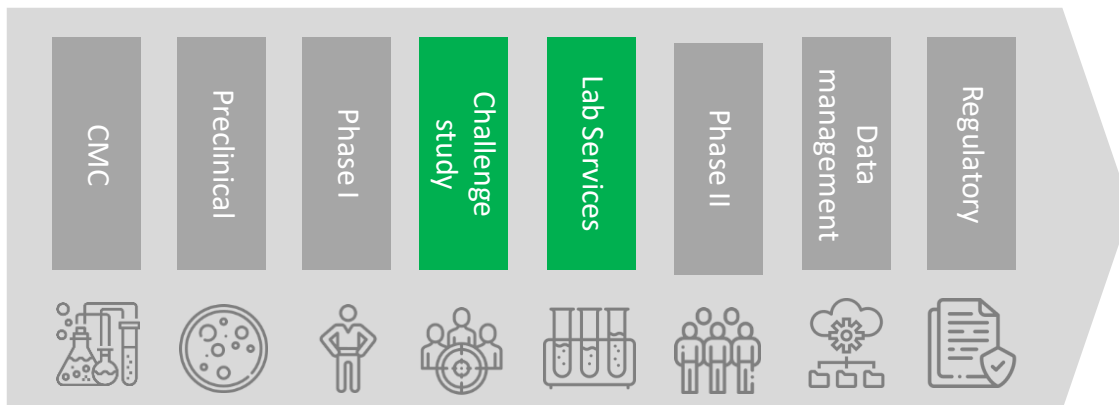


## Industry leading services provider in viral challenge studies and laboratory services

### Overview

- Unique cashflow positive CRO with large upfront cash payment on signing and regular milestone payments
- Founded in 1989 – spin out Queen Mary University
- AIM listed 2012 – HVO
- Approx. 118 employees<sup>(1)</sup>
- Revenue: £13.3m<sup>(2)</sup> in 2018
- World leading portfolio - 2 FLU, 2 RSV, 1 HRV, 1 Asthma, 1 Cough and 1 COPD viral challenge models, coronavirus challenge model under development
- State of the art unit & laboratory, London
- A very extensive asset portfolio

### Current capabilities



### Turnaround / Strategy

- Refocused the business model away from drug discovery and towards profitable CRO and laboratory services
- Business turnaround and headcount reductions implemented
- Annualised cost savings of £11m vs. 2017 – removed 43 roles to reduce costs by £4.4m (incl. £3.5m<sup>(3)</sup> from the removal of 19 management roles)
- Further rationalisations in 2020

### Established Global customers and collaborations



Note <sup>(1)</sup>: Comprised of permanent/fixed-term contract and interim/bank staff. Note <sup>(2)</sup>: Includes Darpa revenue of £2.3m classed as Other Income . Note <sup>(3)</sup>: The net saving is £3.5m, allowing for replacement costs and salary increases post April 2018

# hVIVO - competitive position



**Industry leading  
services provider in  
viral challenge  
studies and  
laboratory services**

## **Dominant market position in viral challenge studies**

- Largest range of viral challenge models and experience in GMP<sup>1</sup> virus manufacturing
  - Specialist know-how and insights invaluable to customers developing vaccine and antiviral products
- Three virus types available in 8 validated challenge models: FLU<sup>2</sup>, RSV<sup>3</sup> and HRV<sup>4</sup>
- No other challenge study service provider in the world has a fraction of the 8 models that hVIVO has
- Purpose-built quarantine unit and laboratory with high levels of infection control allows multiple studies and virus-types to be used simultaneously

## **High barriers to entry limit competition**

- Cost and complexity of virus manufacture and characterisation (8 viral models which would take in excess of £25m and many years to attempt to replicate by any competitor)
- Establishment of a single viral challenge model not straightforward – can take up to 6 years
- Need for specialist facilities, staff, and experience
- Established one of the only validated RSV challenge models commercially available and developed additional older population model
- Established large volunteer pool - critical to source susceptible subjects to meet recruitment requirements
- Central London unit location attractive to volunteers
- Only one commercial competitor in flu challenge in Europe and one in US
- Other competition from academic groups and US government funded organisations have limited capability to deliver larger studies quickly as demanded by larger pharmaceutical companies

# Cross-selling model



## Cross-selling of hVIVO and Open Orphan Services already underway

January 2020 – joint customer proposals underway				Comments
	Customer A	Customer B	Customer C	
CMC	✓			<ul style="list-style-type: none"> <li>For the first time in hVIVO's history it is now pitching for both challenge studies and the natural, much higher value, follow-on phase II field trial study, using the Venn expertise and capability</li> <li>hVIVO is now using Venn's Data Management, Medical Writing, and Statistical capability in all of its customer proposals</li> <li>This will be the catalyst for significant revenue growth and margin expansion within the business</li> <li>Venn now able to run its phase I studies in hVIVO's London clinic as opposed to renting other clinics at high cost</li> <li>Cross-selling of Phase I studies important near-term combined operational synergy</li> </ul>
Phase I	✓			
Challenge study	✓	✓		
Phase II	✓	✓	✓	
Lab support	✓	✓	✓	
Data management	✓	✓		
Medical writing	✓	✓	✓	

# Changing to higher value, longer term contracts, post merger

## New combined revenue growth model



### Existing hVIVO revenue model

Engaged in discussions but no in-house capability

Following the challenge study client moves into field trials i.e. phase II. hVIVO has no in-house capability to perform field trials but there is customer demand

Challenge study

Lab Services

Typical contract value  
**£3-5m**

Customer relationship  
**2-3 year**

### Existing Open Orphan revenue model

CMC

Preclinical

Phase I

Phase II

Data mgmt.

Regulatory

Typical contract value  
**£0.5-7m**

Customer relationship  
**1-8 year**

### NEW COMBINED REVENUE MODEL

- Broader customer base/wider range of services reduces impact of demand fluctuations
- Offers revenue generation from first engagement
- Generates substantial new revenues from areas where previously no capability in hVIVO i.e. phase II clinical trials
  - i.e. CMC, preclinical, phase I, phase II, data management, statistics consulting and support now all provided by Open Orphan
- Offer capability to continue relationship into phase II field trials support

Typical contract value  
**£10-20m**

Customer relationship  
**3-8 year**

***New model should enable customer relationships to last 3-8 years, generating extra revenues over the entire duration and at significantly higher levels, up to £20m per customer if phase II trial work is gained***

# Development assets: Imutex

Open Orphan management team optimistic as to the potential to monetise these assets



## Overview

- In April 2016 hVIVO formed Imutex Limited (“Imutex”) with the SEEK Group to develop vaccines against influenza (FLU-v) and universal mosquito-borne diseases (AGS-v)
- hVIVO contributes management oversight over the future direction of the development of the vaccine candidates, but makes no capital investment to the ongoing development work undertaken
- The most advanced asset is FLU-v, a robust and differentiated advanced-stage influenza vaccine candidate. Imutex is also establishing schedules for meetings with key regulatory authorities, FDA and EMEA, where it hopes to gain further insight into some of the key areas of interest expressed by potential partners
- An additional early stage asset, AGS-v, is an experimental vaccine designed to protect against many different mosquito-borne diseases
- hVIVO owns 49% of Imutex and both assets are wholly owned by Imutex

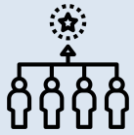
## Assets

Candidate	Phase				Status
	Pre-clinical	I	II	III	
<b>FLU-v</b> <i>Influenza</i>					<ul style="list-style-type: none"><li>• Safety and immunogenicity endpoints met in Phase II field study (UNISEC Consortium in the EU) and efficacy endpoints met in a challenge study in collaboration with NIAID/NIH</li><li>• Scheduling end of Phase II meetings with FDA &amp; EMEA</li></ul>
<b>AGS-v</b> <b>AGS-v PLUS</b> <i>Mosquito-borne Diseases</i>					<ul style="list-style-type: none"><li>• <b>AGS-v</b> Phase Ib study completed by NIH – Preliminary results positive, complete results expected in due course</li><li>• <b>AGS- PLUS</b> Second Phase I study commenced July 19 by NIH – additional peptide</li></ul>

# Aiming for substantial revenue growth & profitability

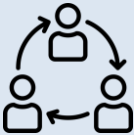


## POSITIONED FOR PROFITABILITY



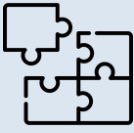
**A platform of highly specialised differentiated service providers**

- hVIVO's specialist services and expertise in respiratory and infectious diseases complement Open Orphan's focus on the rare and orphan drug consulting services platform
- European market is highly fragmented beyond the largest multinationals who focus on larger standardised clinical offerings, thus enabling specialist CROs/service providers to hold significant market share within specialist areas



**Cost synergies**

- Data management services, rationalisation of duplicative IT and enterprise systems, reorganisation of management function/roles, duplicative public company costs and adviser fees
- Phase I studies, which are currently outsourced, delivered in-house using existing resources and capacity



**Revenue growth opportunities**

- The group will be able to provide clients with a more complete offering including: CMC, pre-clinical, phase I, phase II, challenge studies, lab services, data management and regulatory work
- Opportunity to gain revenue over the full-time course of the relationship



**Enhanced Leadership team track record**

- Entrepreneurial leadership team have a track record of establishing, restructuring, repositioning, and building profitable companies and rewarding shareholders