

Open Orphan plc

**Investor Presentation
June 2020**

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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 17th 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 3rd 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

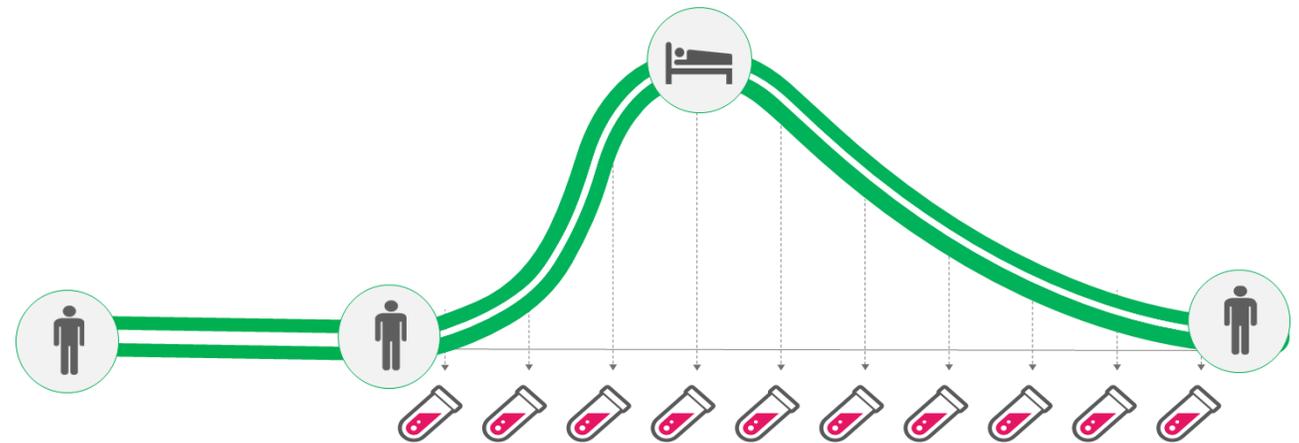
- Currently c.100 Covid-19 vaccines in development around the world, in dialogue with 12 of the leading vaccine developers
- hVIVO 24 bed quarantine clinic, replacement cost c. £25m
 - can be made into 3 zones of 8 beds each so as to run 3 different vaccine company's studies at the same time
- The average 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

6th 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 23rd April

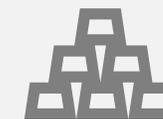
In the past hVIVO mainly serviced its internal lab



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 11th 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



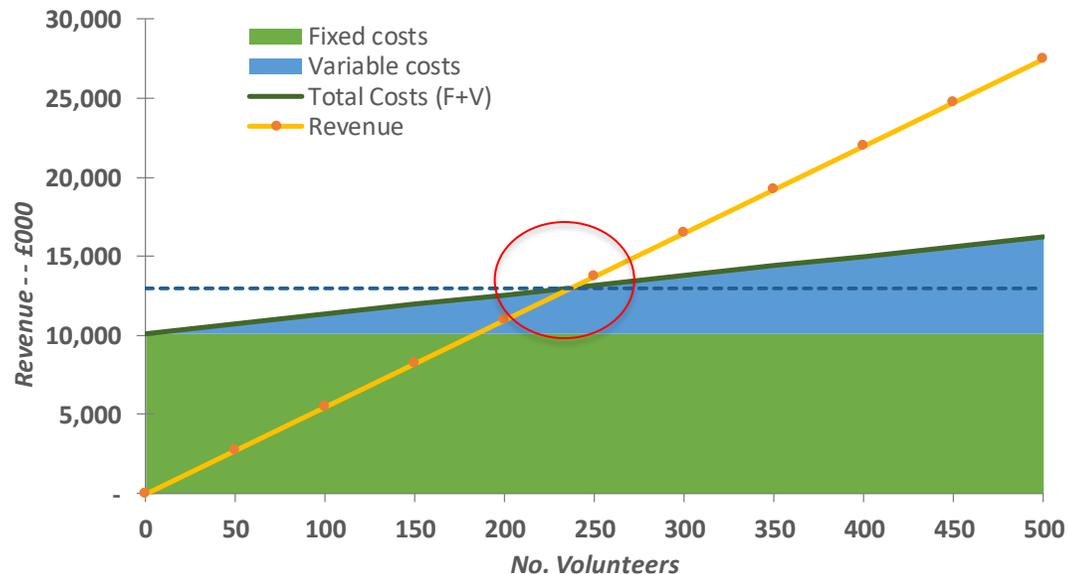
Significant operational leverage – hVIVO



Illustrative breakeven analysis of challenge study and laboratory services

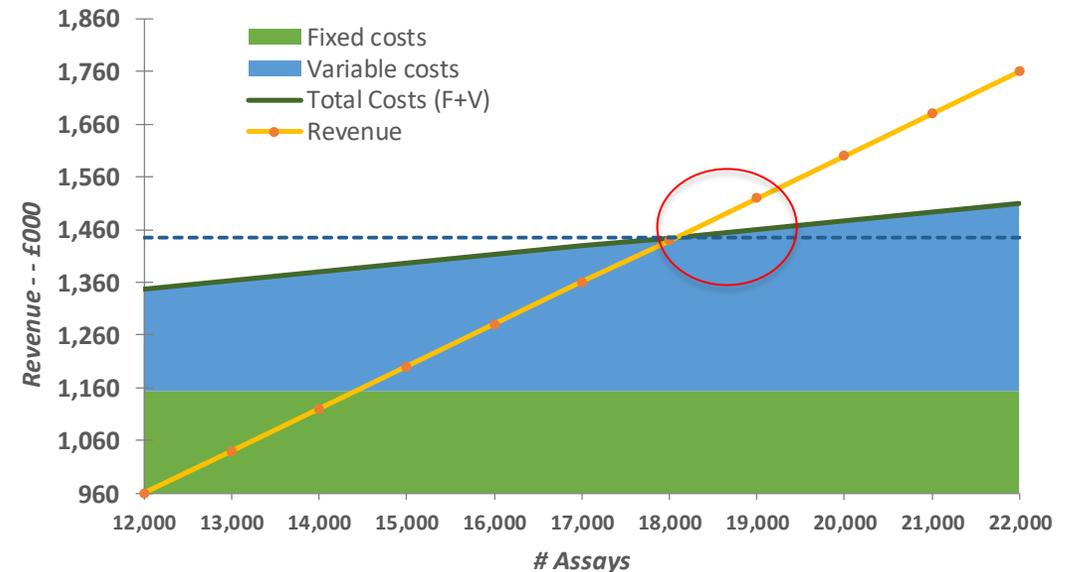
Estimated EBIT break-even point for challenge study clinic of ~£13m revenue i.e. 3 – 4 typically-sized studies and a unit utilisation rate of ~45%

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: 6th of March £3.2m RSV study, with £7m follow-on study, 4th 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 - 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

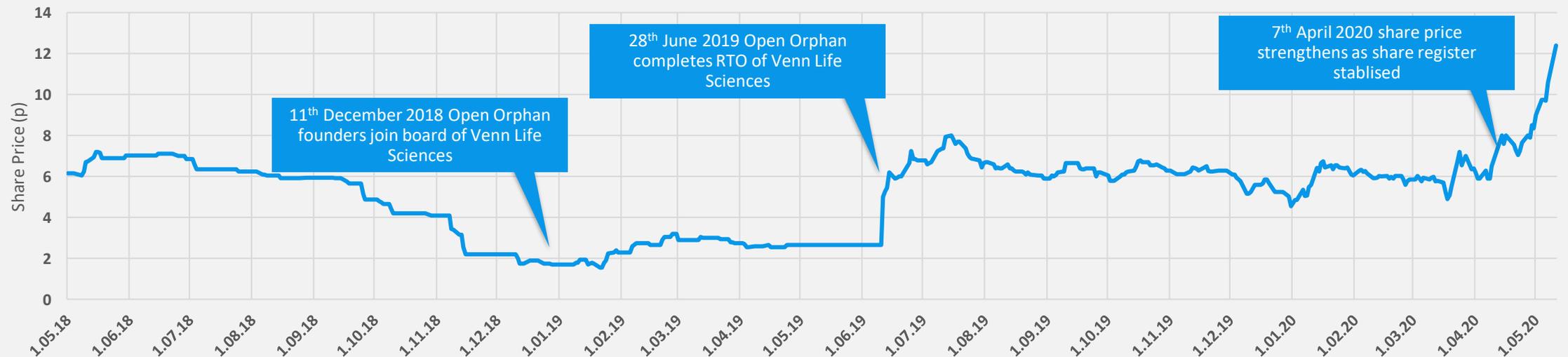
Share price has strengthened since removal of overhang in the past month



May 2020 Fundraise
Heavily oversubscribed
institutional
placing



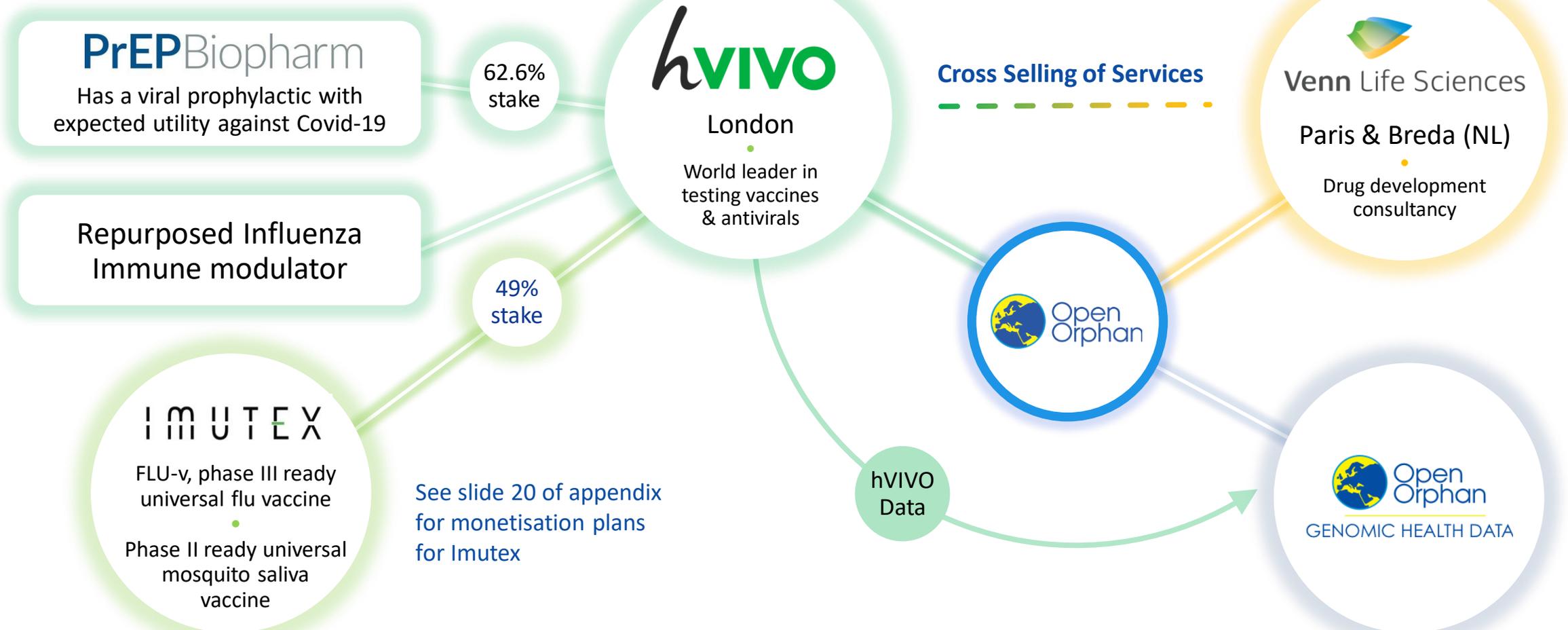
Open Orphan Share Price



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



I M U T E X

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):

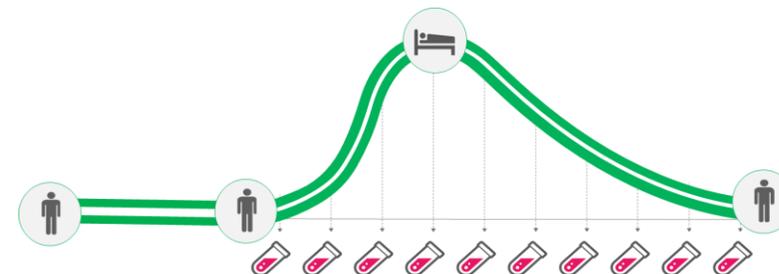
- The Human Viral Challenge (HVC) model has, for many decades, helped in the understanding of respiratory viruses and their role in disease pathogenesis. In a controlled setting, using small numbers of volunteers removed from community exposure to other infections, volunteers are inoculated by known 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

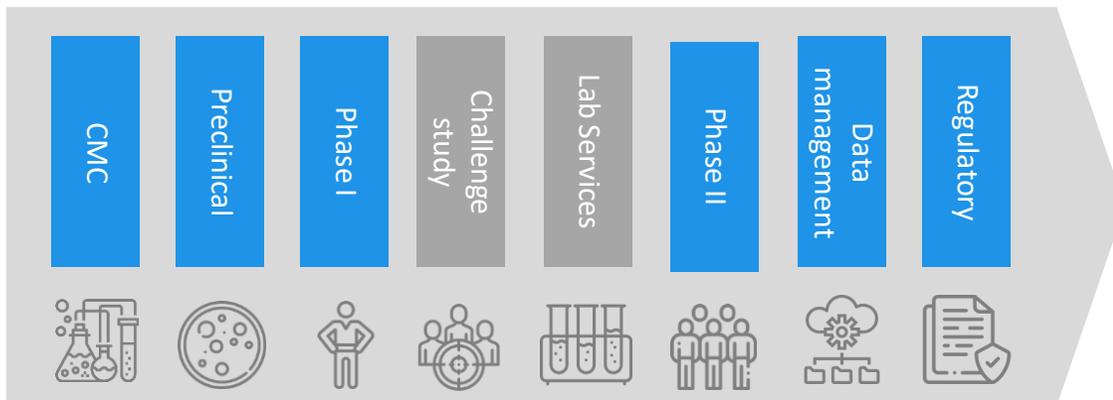


Building a leading European rare/orphan disease focused pharma services company

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), Carna 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

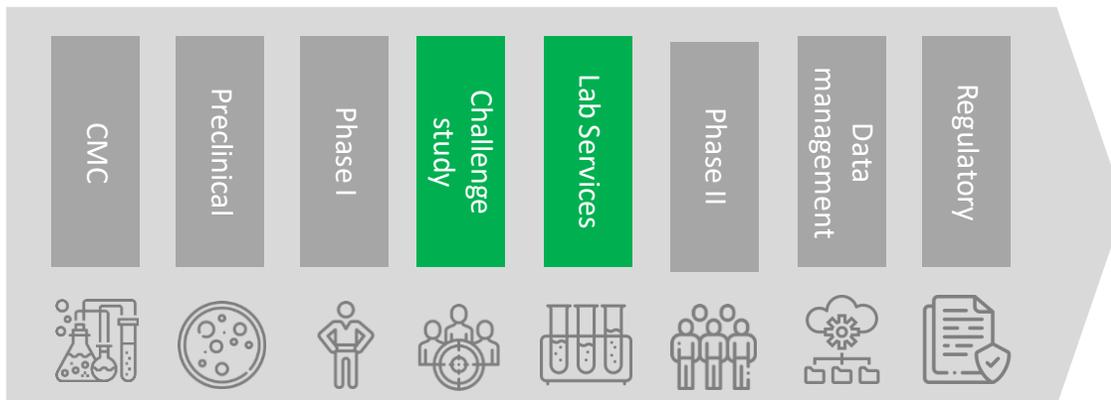


Industry leading services provider in viral challenge studies and laboratory services

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⁽¹⁾
- Revenue: £13.3m⁽²⁾ 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⁽³⁾ from the removal of 19 management roles)
- Further rationalisations in 2020

Established Global customers and collaborations



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

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 GMP¹ virus manufacturing
 - Specialist know-how and insights invaluable to customers developing vaccine and antiviral products
- Three virus types available in 8 validated challenge models: FLU², RSV³ and HRV⁴
- 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			
	Customer A	Customer B	Customer C
CMC	✓		
Phase I	✓		
Challenge study	✓	✓	
Phase II	✓	✓	✓
Lab support	✓	✓	✓
Data management	✓	✓	
Medical writing	✓	✓	✓

Comments

- 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
- hVIVO is now using Venn’s Data Management, Medical Writing, and Statistical capability in all of its customer proposals
- This will be the catalyst for significant revenue growth and margin expansion within the business
- Venn now able to run its phase I studies in hVIVO’s London clinic as opposed to renting other clinics at high cost
- Cross-selling of Phase I studies important near-term combined operational synergy

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



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

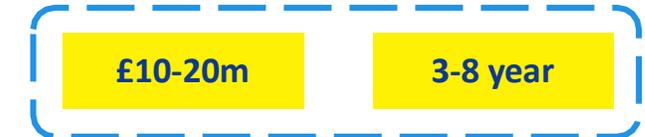
- Broader customer base/wider range of services reduces impact of demand fluctuations
- Offers revenue generation from first engagement
- Generates substantial new revenues from areas where previously no capability in hVIVO i.e. phase II clinical trials
 - i.e. CMC, preclinical, phase I, phase II, data 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

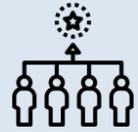
Assets

Candidate	Phase				Status
	Pre-clinical	I	II	III	
FLU-v <i>Influenza</i>					<ul style="list-style-type: none"> • 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 • Scheduling end of Phase II meetings with FDA & EMEA
AGS-v AGS-v PLUS <i>Mosquito-borne Diseases</i>					<ul style="list-style-type: none"> • AGS-v Phase Ib study completed by NIH – Preliminary results positive, complete results expected in due course • AGS- PLUS Second Phase I study commenced July 19 by NIH – additional peptide

Aiming for substantial revenue growth & profitability

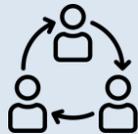


POSITIONED FOR PROFITABILITY



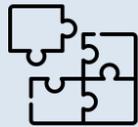
A platform of highly specialised differentiated service providers

- 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