

Open Orphan plc

**Investor Presentation
January 2020**

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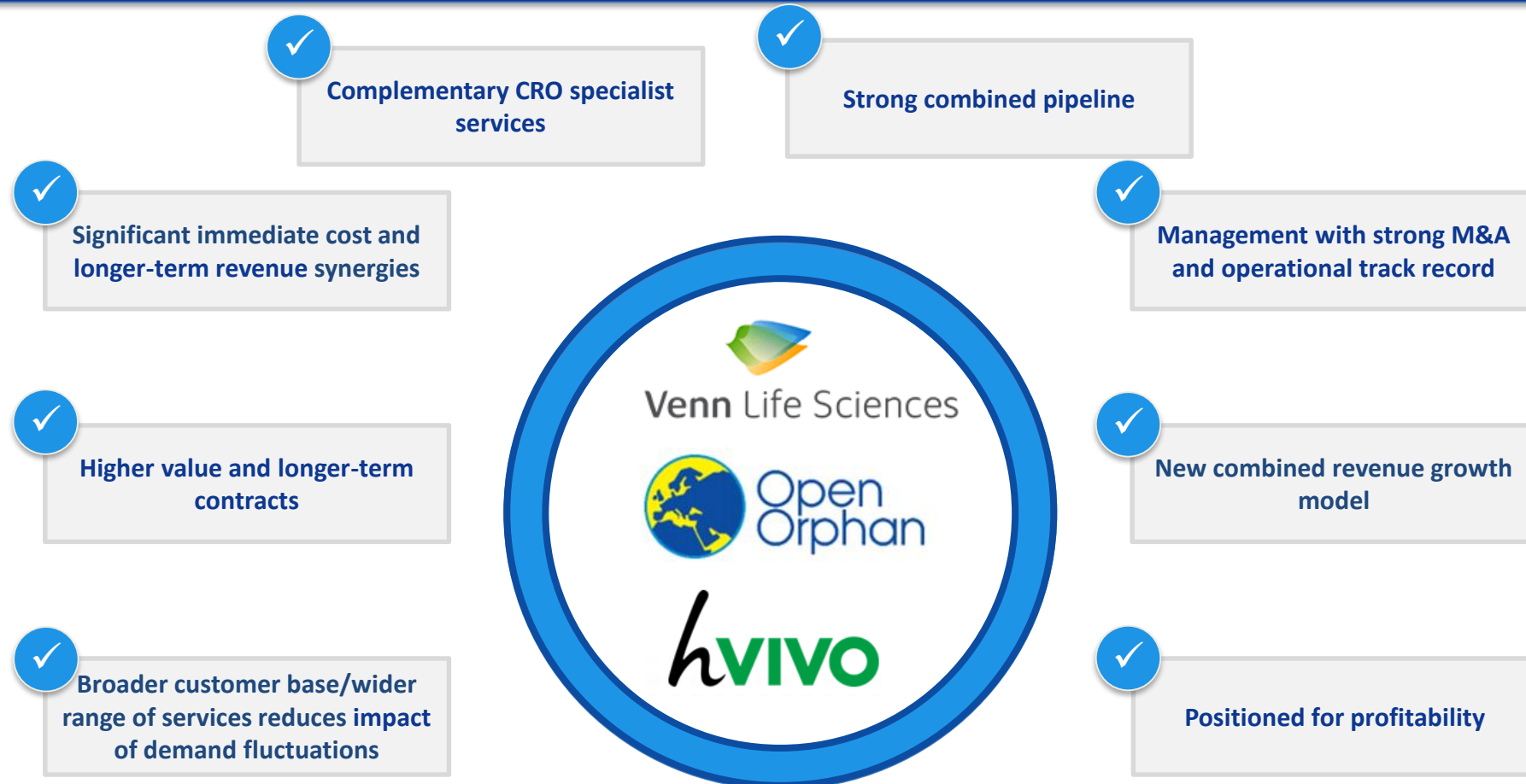


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A compelling strategic combination



UNLOCKS POTENTIAL FOR SUBSTANTIAL REVENUE GROWTH & PROFITABILITY



Creating a European full pharma services company

Management with strong M&A and 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



Trevor Phillips Chief Executive Officer, Director

- Over 30 years of experience within pharmaceutical industry, including international drug development and corporate development responsibilities
- Previously COO & President of US Operations as well as Board Director at Vectura Group plc
- Served as CEO at Critical Therapeutics, Inc. leading the merger of the company with Cornerstone BioPharma Holdings



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



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



Creating a European full pharma services company



Open Orphan Plc

hVIVO services



- Viral challenge studies for:
 - Antivirals
 - Vaccines
 - Respiratory disease agents

Laboratory services – highly specialised virology, immunology & respiratory

Venn services



- Integrated drug development consultancy
- Offers CMC¹, preclinical, phase I & II clinical trials design and execution
- Also offers post trial data management and regulatory expertise

Open Orphan Data

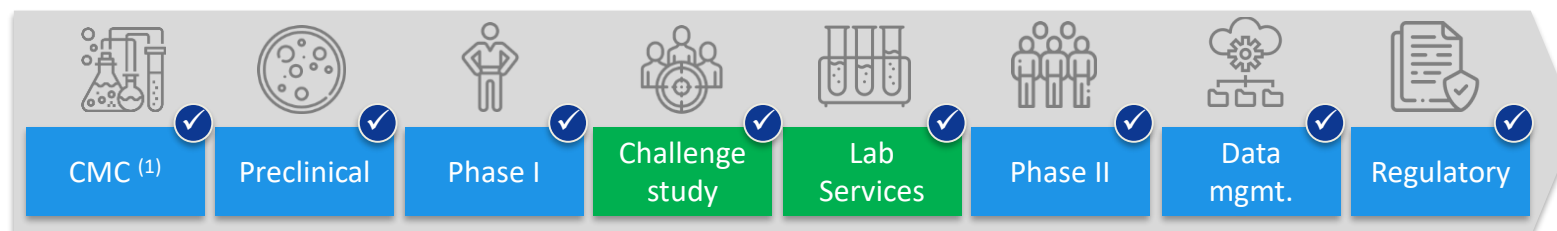


- Orphan drug genomics data platform
- Captures valuable genetic data from patient populations with specific diseases with designated orphan drug status
- Incorporates AI tools
- Pharma companies already on board as clients
- Potential to utilise hVIVO patient data

Post merger capability

■ hVIVO capability

■ Venn capability



Opportunity to gain revenue over the full-time course of the relationship development life cycle

Global CRO market forecast to reach \$44bn in 2021, growing at 12% per annum⁽²⁾

Notes: ⁽¹⁾ Chemistry, manufacturing and controls

⁽²⁾ The Business Research Company

Imutex Ltd



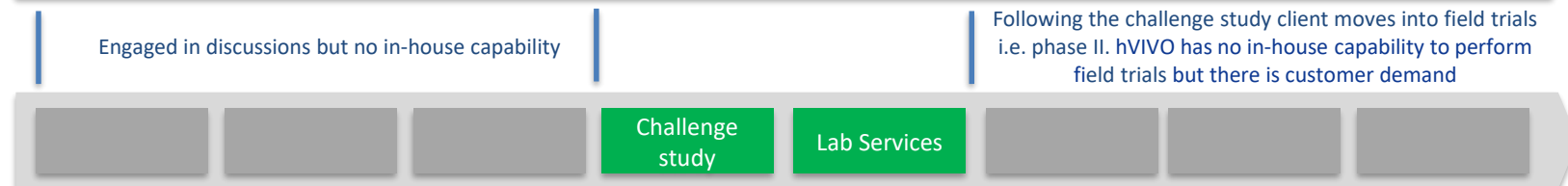
- 49% stake in Imutex Ltd JV
- Previous hVIVO management formed Imutex Ltd in a JV with the SEEK Group
- No further capital investment being made
- Development of vaccine candidates
- FLU-v, a phase III ready universal influenza vaccine candidate
- AGS-v, a phase I vaccine candidate for mosquito-borne diseases
- Open Orphan management team optimistic as to the potential to monetise these assets

Higher value and longer-term contracts

New combined revenue growth model



Existing hVIVO revenue model



Typical
contract value

£3-5m

Customer
relationship

2-3 year

Existing Open Orphan revenue model



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 trial 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

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

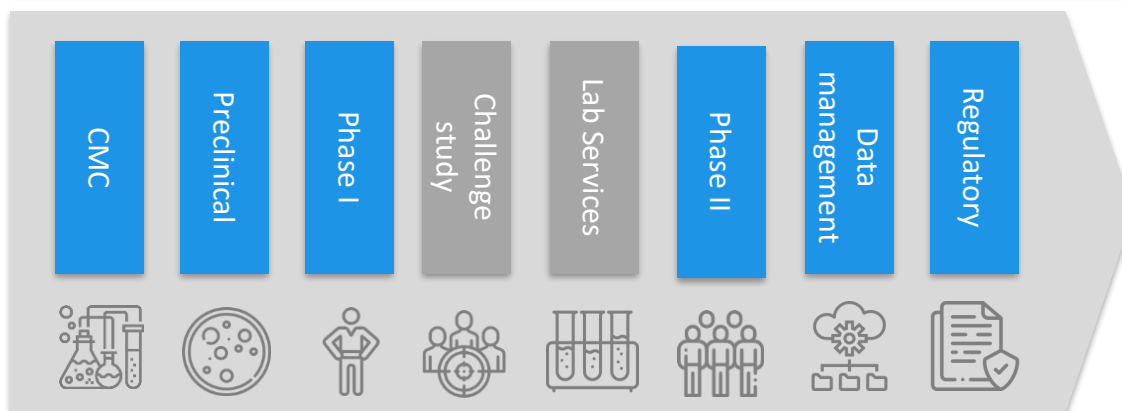
Overview

- Acquired AIM-listed Venn in June 2019 in RTO
- AIM & Euronext listed – ORPH
- Approx. 120 employees and dropping to 100 end Q1 , from 176 in 2018
- Revenue: €14.3m in 2018
- Offices in Dublin, Paris, Breda (Netherlands)
- Mgmt. own 19.5% pre-merger (post merger c. 7.8%) under a 3 year lock-up
- Over 400 studies completed in last 10 years, including 63 rare disease trials

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 in June 2019 – reducing headcount from 176 to 100 end Q1 2020, removing up to €3.85m from annualised cost basis including 3 offices 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

Current capabilities



Established Global customers and collaborations



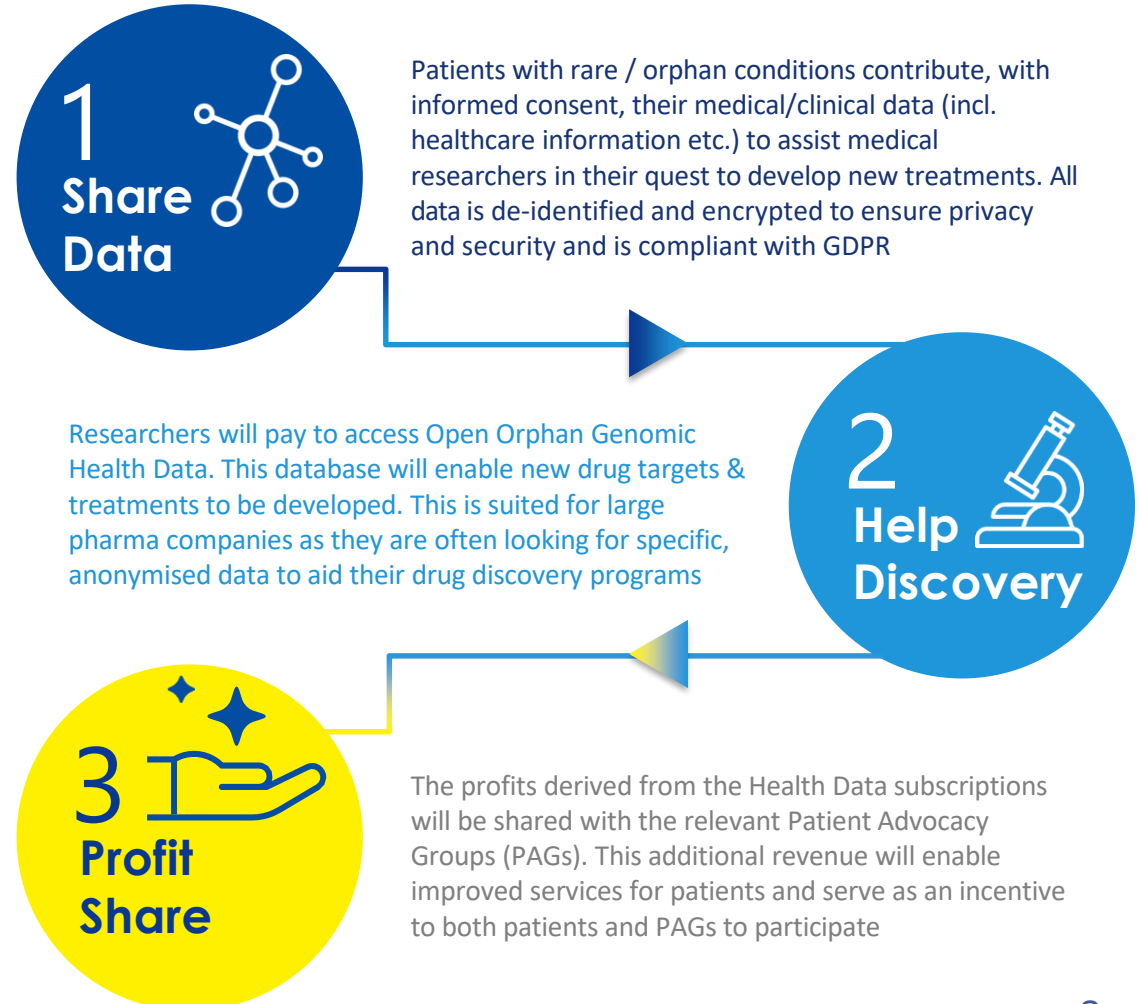
Open Orphan's Genomic Health Data Platform capturing valuable genetic data incorporating AI tools



Genomic Health Data Platform

- Aiming to become a leading EU broker of rare disease patient data
- Platform is in the final phase of development prior to accepting first data
- A number of Early Adopters already signed up to the platform
- Low cost data collection model; the data already pre-exists and using GDPR rules to facilitate same
- Assists in drug discovery for genetic rare diseases and helps pharma companies identify patients for clinical trials
- In-house developed Artificial Intelligence tools allow us to scale platform rapidly
- Potential for hVIVO's existing respiratory patient data to be hosted and monetised on the platform

How the platform will work



Industry leading services provider in viral challenge studies and laboratory services

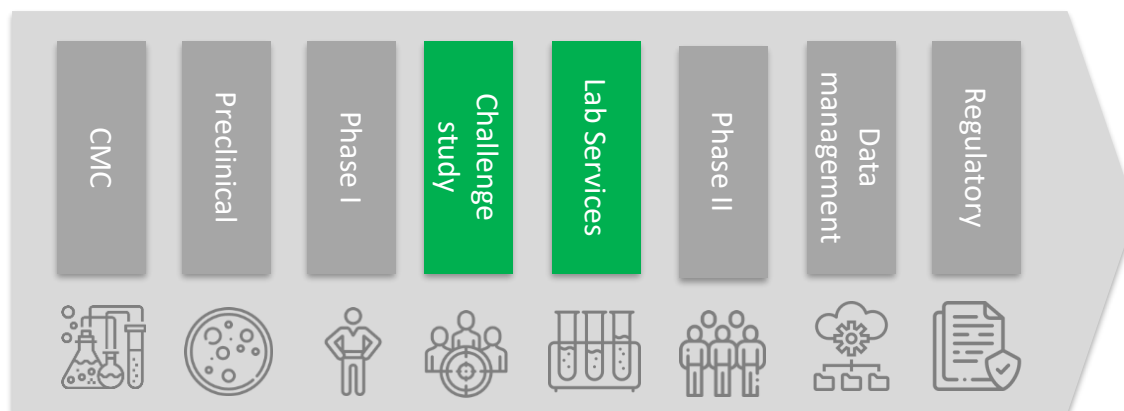
Overview

- 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
- State of the art unit & laboratory, London
- A very extensive asset portfolio

Turnaround / Strategy

- New management team from 2018, focused on turning around the company
- Refocused the business model away from drug discovery and towards —CRO services
- Business turnaround with operational efficiency measures 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

Current capabilities



Established global customers and collaborations



hVIVO – a very extensive asset portfolio

c.£100m was raised which has been invested in hVIVO's state of the art labs and support its state of the art clinic, lab, challenge study models, and former drug discovery strategy

May-2012 IPO: £15m

- Funding used to create state of the art unit and lab facilities
- Establishing new challenge models in Flu and RSV
- Some funds directed towards new drug discovery strategy

June-2013: £26m

- Creation of airways disease viral exacerbation challenge model
- Further investment in drug discovery division

August-2014: £34m

- Investment in asthma and COPD challenge models
- Enhancement of discovery platform for new Flu targets

November-2015: £21m

- Investments into drug discovery (PrEP and Imutex)
- 49% ownership of Imutex with no further capital commitment

...this has resulted in a high quality bespoke 24-bed quarantine clinic in London combined with a GLP analytical laboratory supporting human challenge studies and the worlds leading portfolio of 8 viral challenge models, pre-clinical & clinical trials

London unit



London lab



hVIVO today has a leading portfolio of 2 FLU, 2 RSV, 1 HRV, 1 Asthma, 1 cough and 1 COPD¹ 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

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 - takes 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

Complementary CRO specialist services



Cross-selling of hVIVO and Open Orphan Services already underway

December 2019 – 3 joint customer proposals were made

Comments

	Customer A	Customer B	Customer C
CMC	✓		
Phase I	✓		
Challenge study	✓	✓	
Phase II	✓	✓	✓
Lab support	✓	✓	✓
Data management	✓	✓	
Medical writing	✓	✓	✓

- 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

Robust combined pipeline



HVIVO - SOLID PIPELINE

	Opportunity Name	Virus	Volunteers	Contract value
1	Client A: Pilot RSV Challenge	RSV	38	£2.4m
2	Client A: Main RSV Challenge	RSV	120	£7.2m
3	Client B: Universal FLU Vaccine	FLU	150	£6.3
4	Client C: RSV Attenuated Virus Vaccine	RSV	68	£4.5m
5	Client D: Flu Challenge	FLU	72	£3.4m
6	Client E: Diagnostic Device Exploratory Challenge	FLU/RSV	66	£2.8m
7-22	Other high-probability contracts	FLU/RSV/HRV	1,152	£54.6m
TOTAL			1,666	£81.2m

- Solid pipeline of identified and pitched for contracts as at January 2020 is **£81.2m** significantly greater since new management implemented– January 2018: £37.8m, January 2019: £39.4m
- 46% of January 2018 high probability pipeline value converted into signed contracts during FY18 and similarly a 42% conversion in FY19⁽¹⁾

Not all signed contract value is recognised as revenue in the year the contract was signed, often a proportion continues into the following year as contract delivered

Note: ⁽¹⁾ Conversion to sales excluding cancellations

OPEN ORPHAN - BUILDING RECURRING REVENUES

- Venn moving away from short-term contracts to long term, 3-year contracts with recurring revenues
 - IPSEN, Carna Bioscience – signed (Nov '19)
 - German Tier One – signed (Jan '20)
 - Over €10.5m in confirmed backlog with an additional €4.0m at an advanced stage with clients under existing MSAs
 - Approx. €10.0m in budget proposals under review with clients

COMBINED PIPELINE EXPECTED TO DELIVER SIGNIFICANT GROWTH & PROFITABILITY

The Directors believe there is significant valuation uplift potential as the combined business demonstrates profitability, with profitable CROs trading at a revenue multiple of 2-3x (e.g. Ixico & Ergomed)

Immediate operational and longer-term revenue synergies



ESTIMATED OPERATIONAL SYNERGIES:



Elimination of subcontractor costs

- Proportion of the Phase I studies, including laboratory services, currently sub-contacted by Open Orphan being delivered by hVIVO utilising existing resources/spare capacity: **up to £1.7m in FY2020 increasing to £2.3m in FY2021**



- Data management, statistics, medical writing, regulatory and project management, which are currently sub-contracted either in part, or in full, by hVIVO being delivered by Open Orphan utilising existing resources/spare capacity: **up to £0.6m in FY2020 increasing to £0.8m in FY2021**



Rationalisation

- Rationalisation of duplicative IT and enterprise systems, reorganisation of management function/roles, duplicative public company costs and adviser fees: **up to £0.7m in FY20 increasing to £0.9m in FY2021**
- In addition to the already substantial headcount reductions in Venn and hVIVO there are further cost synergies in the finance function, back-office, staff, and office space - **up to £0.2m in FY20 ⁽¹⁾ increasing to £0.4m in FY2021**

ESTIMATED TOTAL OPERATIONAL SYNERGIES: £3.1M FY2020, INCREASING TO £4.4M IN FY2021

OPERATIONAL SYNERGIES AS % OF COMBINED STANDALONE OPERATING COSTS⁽²⁾: FY2020 – 10%, FY2021 – 12%

POTENTIAL FUTURE SIGNIFICANT REVENUE SYNERGIES:



Longer-term significant revenue synergies

- Extending hVIVO relationships - utilising Phase II capability of Open Orphan to gain contracts for Phase II execution and lab services as existing challenge customers migrate to field trials – **not yet valued**

Ongoing cost reduction programmes



Open Orphan / Venn:

- Substantial overhead reduction underway since RTO in June 2019
- Headcount reduction in progress from 176 to 100 expected to complete Q1 2020
- Overall reduction of up to £3.85m from the annualised cost base, to be completed by end 2020

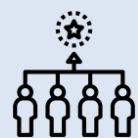
hVIVO:

- Significant reduction in administrative expenses driven by headcount reductions and process improvements, and R&D expenses due to discontinuation of discovery activities
- £11m removed from annual overhead since 2017
- 194 staff in 2017 reduced to 118 (all staff) in December 2019
- Further rationalisations in 2020

Aiming for substantial revenue growth & profitability

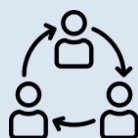


POSITIONED FOR PROFITABILITY



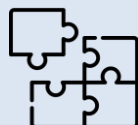
A platform of highly specialised differentiated service providers

- 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 1 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

- Leadership team of hVIVO have a track record of restructuring and re-positioning for profitability, having implemented operational and headcount reductions providing significant cost savings going forward
- Annualised cost savings of £11 million vs. 2017 – removed 43 roles to reduce costs by £4.4m, (incl. £3.5m from the removal of 19 management roles⁽¹⁾)

Note: ⁽¹⁾ The net saving is £3.5m, allowing for replacement costs and salary increases post April 2018

Appendix – Additional information on hVIVO plc

Refocussing the business model



hVIVO

2018 was a
transitional year
and the beginning
of the turnaround



New management team

Significant restructuring – almost entire senior management replaced
Reskilled business necessary to perform services & added staff and capability to enhance existing CRO team



Prioritised services business model

Discontinued discovery activities, reducing R&D costs significantly



Cost reduction and operational efficiency programme commenced

Multiple actions taken to reduce cost including headcount, processes, premises and systems



Sales & Marketing refocus and positioning

Adapted messaging to reinforce perception as leading customer-focussed challenge services business with strong track record in Flu and RSV and competitive pricing



Expanded and diversified service offering

Developed new models to offer broader range of services and more consistent revenue streams

2019 positioning for profitability

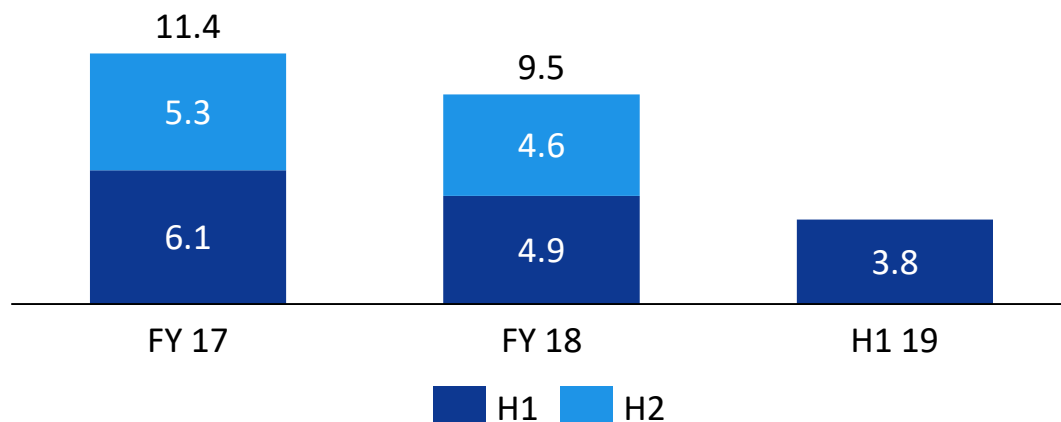
- Significant cost reductions and operational efficiencies implemented since FY2018 expected to drive FY2020 operating costs down by £11m compared to FY2017
 - Strong pipeline of contract opportunities for 2020

Restructuring to date

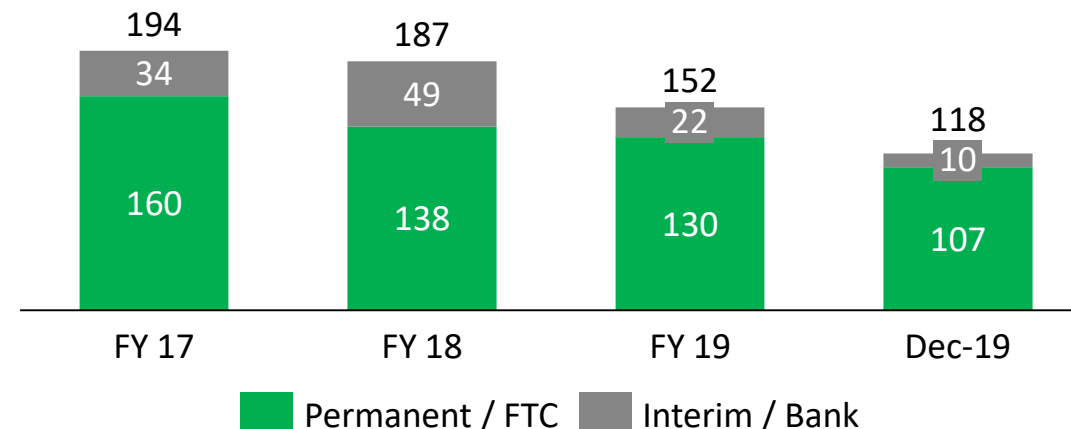
The new management team has made a number of changes

- Refocused the business model away from drug discovery and towards the provision of human challenge study services
- The shift in business model has led to a significant reduction in administrative expenses driven by headcount reductions and process improvements, and R&D expenses
- Annualised cost savings of £11 million vs. 2017 – removed 43 roles to reduce costs by £4.4m, (incl. £3.5m from the removal of 19 management roles)⁽²⁾

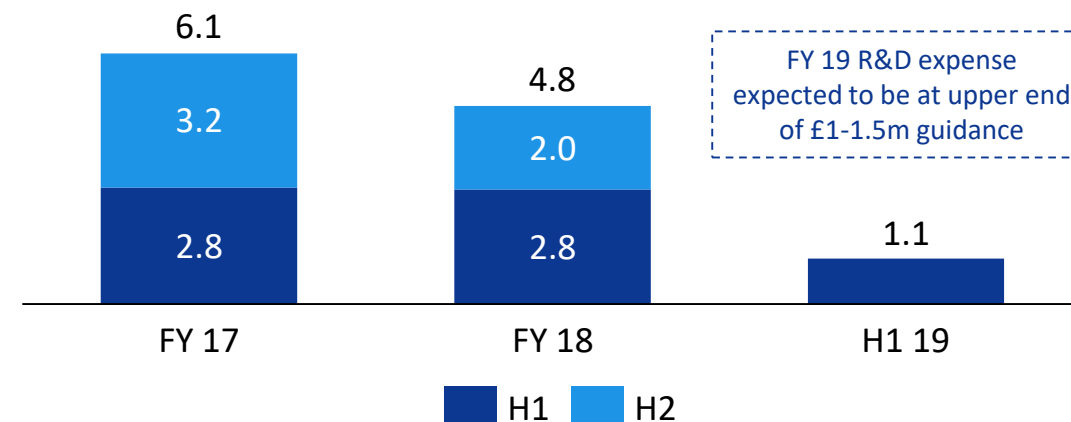
Admin expense development (£m)



Headcount development⁽¹⁾



R&D expense development (£m)



New service offerings by hVIVO



1. Phase I studies

- hVIVO Quarantine Unit well suited for Phase I Studies
- Company traditionally not conducted First Time in Man studies (FTIM)
 - Preferred to sub-contract to specialist Phase I units in London
- Now offering FTIM for products that will subsequently move into a challenge study
 - Potential for FTIM work as combined protocol incorporating PII challenge study
 - Reducing development timelines from preclinical to proof of concept
- Potential to add incremental revenue and greater visibility on pipeline status

2. Extended leading position in RSV

- hVIVO has established one of the only validated RSV challenge models commercially available
- Development of an older population model which is more reflective of a major part of the target population for therapies/vaccines – now available to potential customers
 - Pilot study completed – data will be subject of a peer review publication
- Further successful delivery of a customer study in healthy population
 - Enanta EDP-938 data clearly demonstrated efficacy and illustrates the benefit of good challenge data to companies developing novel products
 - Heightening awareness of the value of challenge studies in clinical development

3. Respiratory models

- Respiratory work offers new clinical and laboratory revenue potential
- **Asthma & COPD:** hVIVO challenge models deliver precise and dynamic measurement of asthma/COPD physiology
 - Utilising HRV challenge in asthma and COPD
 - Additional non-challenge study opportunities using respiratory specific endpoints
 - act as a study site for traditional asthma and COPD studies
- **Chronic / acute cough:** hVIVO challenge model provides a unique opportunity for positioning an efficacious drug against chronic and acute cough
 - Conducted first novel cough model study in H2-18

4. Laboratory services extended

- Highly specialised virology and immunology laboratory offering a suite of services to support drug and vaccine discovery and development
- Laboratory services extended to supporting samples generated from field studies
 - Utilising relationships established during servicing of in-house studies to capture sample analyses from subsequent field studies
 - Potential to extend to supporting preclinical activities
- Built on sampling expertise within unit to offer services supporting respiratory biomarker analyses

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