

AIM: POLB
OTCQB: POLBF



Company Presentation

June 2022

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Building a Leading Infectious Diseases Company



Spun out from  Open Orphan

Deep roots in infectious disease & the clinical trials business

Fully funded £25m raised at IPO July 2021



Long term shareholders including leading institutions

Cathal Friel **7.28%**

Schroders Investment Management **5.13%**

Poolbeg has a unique capital light & early monetisation model

Only similar company is Evotec in Germany which has a \$4.7bn market cap. Evotec also has deep roots in the clinical trials business

Targeting booming infectious disease market
Expected value >\$250bn by 2025

Experienced team have previously created c. \$1bn in shareholder value

- **Rapidly expanding portfolio of assets**
- **Self funding business model - out-licensing early and often**
- **Focusing on the European and N. American rights - can sell the China, India, Korea & other market rights for cash**
- **Becoming a one-stop-shop for bigger pharma and biotechs seeking infectious disease assets**

Experienced Leadership Team



Cathal Friel
Chairman



Jeremy Skillington
CEO



Ian O'Connell
CFO



Carol Dalton
VP IR & PR



Patrick Ashe
Non-Executive Director



Prof Luke O'Neill
Non-Executive Director



Eddie Gibson
Non-Executive Director



Operational Highlights

Executing on our strategy – momentum continuing to build

Multiple deals completed

Expansion & diversification of portfolio – reducing risk & increasing upside potential

- ✓ POLB 002
- ✓ POLB 003 + 5 other vaccine candidates under review
- ✓ Oral Vaccine Delivery Platform

Commenced trading on US OTCQB market

March 2022



POLB 001

On track for LPS challenge study in June 2022

Data expected by year end with monetisation to rapidly commence thereafter

Well Capitalised

£20.9m at 31 Dec 2021

Low cash burn & long cash runway

Pursuing non-dilutive funding

2 Artificial Intelligence deals signed

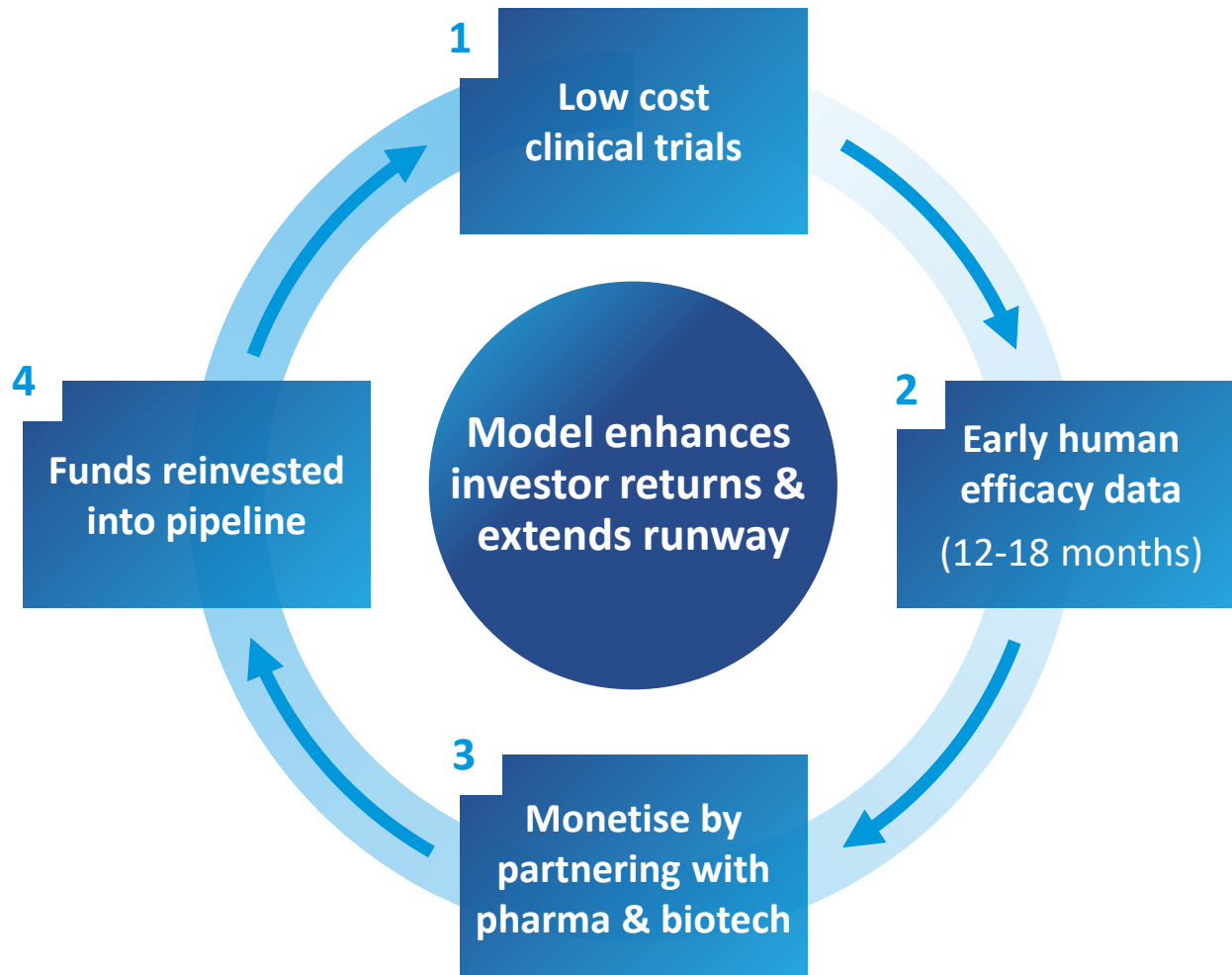
Identify new drug targets & treatments for RSV & Influenza

New Investors offered to purchase £1.6m distribution in specie shares at market price (5.9p) before end of lock-up period

April 2022

Rapid Development & Frequent Out-Licencing

Developing multiple assets at once - reducing risk



Recent infectious disease deals

GSK acquires Affinivax

\$2.1b upfront + \$1.2b follow-on, May 2022
Pneumococcal vaccine & vaccine platform

Pfizer acquired ReViral

up to \$525m, April 2022
Respiratory Syncytial Virus (RSV)

Bav Nordic licence Chinese rights to Nuance Pharma

\$12.5m upfront + \$200m follow-on, Mar 2022
Respiratory Syncytial Virus (RSV)

Merck acquired OncoImmune

\$425m upfront, Nov 2020
COVID-19

Pfizer's Valneva deal

\$130m upfront + \$188m follow-on, April 2020
Lyme Disease

Expanding Pipeline of Assets


Product pipeline

Product Candidate	Program	PreClinical	Phase 1	Phase 2	Phase 3
POLB 001	Severe Influenza treatment	LPS study data expected H2 '22		Monetisation Zone	
POLB 002	Respiratory virus infections treatment & prophylactic				
POLB 003	Melioidosis vaccine*				

Targeting significant upfront payments followed by milestone payments & royalties


Programmes & Platforms

Artificial Intelligence Drug Discovery Programme
Influenza



1st Data - H1 2023

Artificial Intelligence Drug Discovery Programme
Respiratory Syncytial Virus



1st Data - H2 2022

Oral Vaccine Delivery Platform
Developing vaccines for multiple indications

Vaccine Discovery Platform
Identify vaccine candidates from naturally occurring immune response

PredictViral™
Identify patients at risk of developing severe disease early

In active discussions for a range of other assets

POLB 001 - Severe Influenza Treatment

Clinical stage potential blockbuster immunomodulator



June 22 - LPS human challenge trial to commence

H2 22 - Early human efficacy data expected

Plan for early monetisation thereafter

- Trial to gather broad dataset – de-risk and increase value
- Patent protected until 2038, expanding IP
- Worldwide rights for all uses in humans
- Potential peak sales \$275m+ in influenza alone
- Exploring further disease indications – increase value

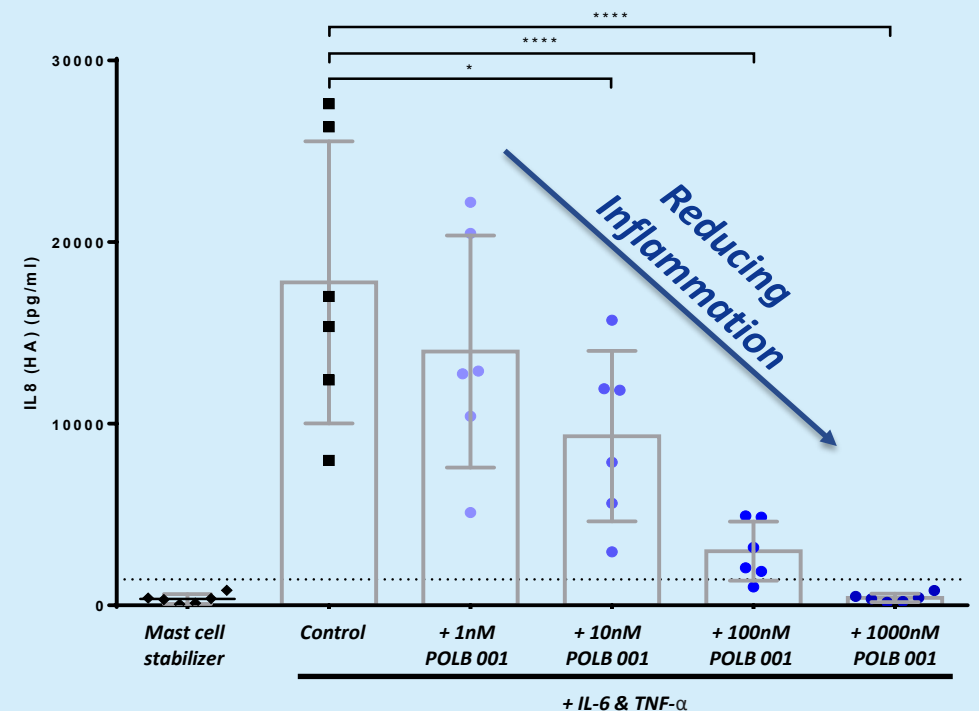
Influenza

1 in 8
of global
population
infected annually

5-10M
hospitalised

500,000
deaths

POLB 001's ability to interrupt the feedback loop of inflammatory mediators that result in a 'cytokine storm' make it an ideal candidate to reduce disease severity for those most at risk



To simulate hyperinflammatory conditions, immune cells were treated with IL-6 and TNF- α , and IL-8 was used as a marker to measure resulting inflammation. The addition of POLB 001 reversed the inflammatory response in a dose dependent manner.

POLB 002 - Respiratory Virus Infection Immunotherapy

First-in-class, broad spectrum, RNA-based

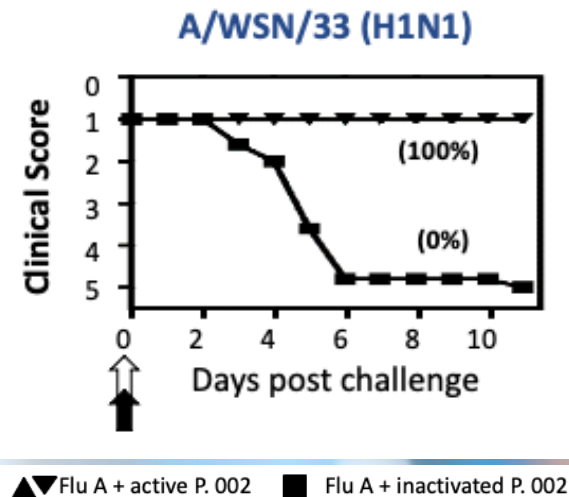
- Late preclinical stage
- Prophylactic & therapeutic
- Delivered intranasally
 - triggers nasal cells into an antiviral state to protect against the virus
 - blocks the virus from replicating

Respiratory Virus Infections

5-20%
global population
infected
by seasonal
outbreaks

3M+
annual deaths
worldwide

Top 5
global cause of
death



A global need for respiratory virus infection products

Most respiratory virus infections cannot be treated

15%

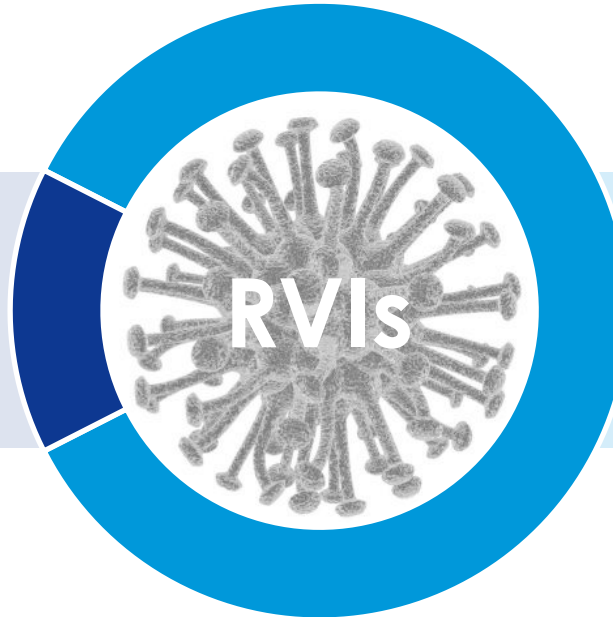
INFLUENZA

VACCINES

Protection variable

ANTI-VIRAL THERAPIES

Require diagnosis of virus type



85%

NON-INFLUENZA RVIS

FEW AVAILABLE
TREATMENTS



United
Nations

UN News

Global perspective Human stories

Infectious diseases 'clear and present danger' everywhere

27 December 2021



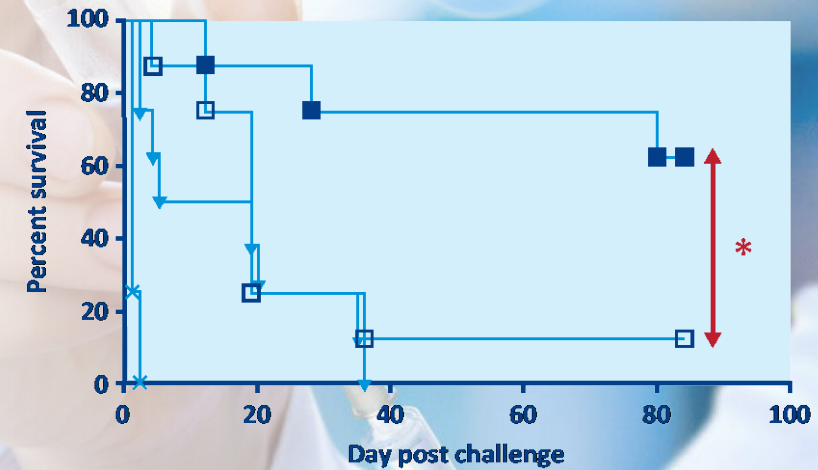
There will be another pandemic, infectious disease experts say.

June 2, 2022

POLB 003 – Melioidosis Vaccine

Potential for non-dilutive funding

- Late pre-clinical stage
- Wellcome Trust funded early development
- Global incidence of Melioidosis rising due to climate change
- CDC designated Tier 1 Select Agent bioterror
- Antibiotic resistant
- Under the agreement with UCD, 5 other vaccine programs are also being evaluated



■ A (protein + SAS) □ B (SAS only) ● C (protein + Alum)
○ D (Alum only) × E (Saline) ▼ F (ZD2)

POLB 003 significantly enhances survival in a murine model of chronic Melioidosis

Melioidosis

165,000

estimated cases per annum

54%

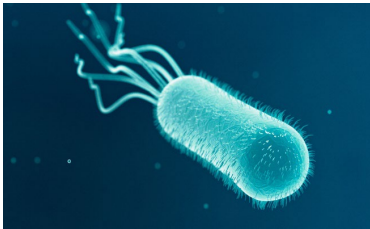
of cases are fatal

0

vaccines available

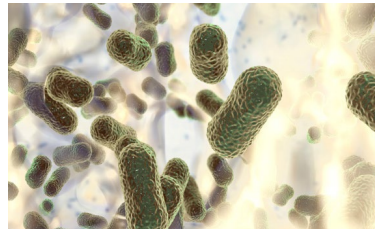
Additional vaccine candidates from UCD

Poolbeg has also agreed an option agreement for 5 additional vaccine antigen candidates which it is currently evaluating



O157 E.coli/STEC/ VTEC

- Lead antigen candidates selected
- Powerful toxin can severely harm children & elderly and leave lasting kidney damage



Acinetobacter baumannii

- Multiple antigens identified
- Prevalent issue in US Defence and healthcare settings, resulting in burdensome management of complications



Pseudomonas aeruginosa

- Multiple antigens identified
- Leading cause of morbidity and mortality in **cystic fibrosis**
- Interest area for National Institute of Health (NIH)



Klebsiella pneumoniae

- Lead antigen candidates selected
- Significant cause of hospital-acquired infections with large impact on health budgets



Burkholderia cepacia complex

- Lead antigen candidates selected
- Poses threat to immuno-compromised patients in care settings such as Cystic Fibrosis patients

Oral Vaccine Delivery Platform

Exclusive licence to encapsulation technology for vaccine generation

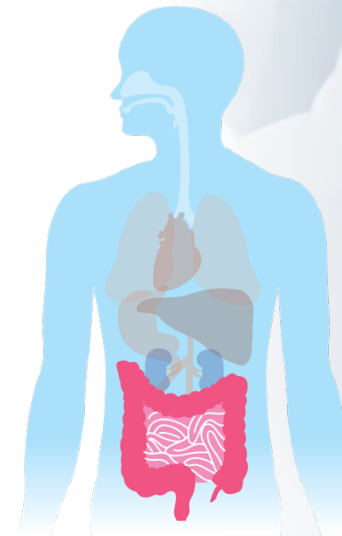
- Developing oral vaccine delivery platform that generates ‘mucosal immunity’
 - Preventing pathogens from infecting the body
 - Prevent transmission of disease
- Easy administration – needle free
- Highly attractive market
- Multiple disease indications

Benefits of Oral Vaccines

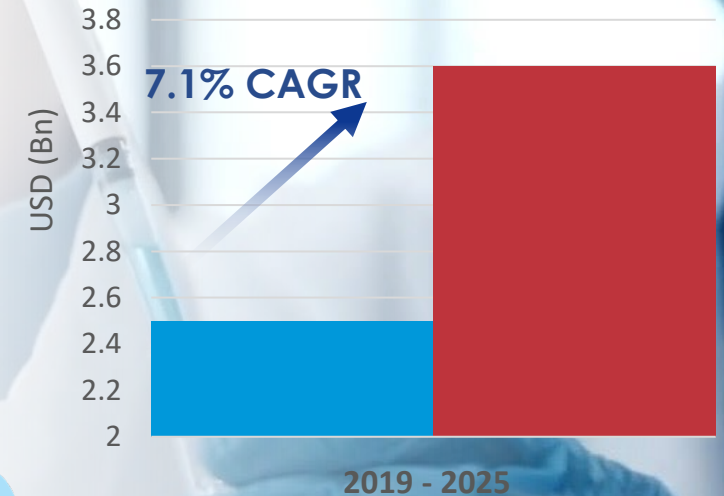
Drives mucosal immunity

Easier distribution & administration

Overcomes needle phobia



Oral Vaccine Market Growth



Market growth reflects significant potential of the mucosal vaccines

Artificial Intelligence

AI Powered Drug Discovery Programmes

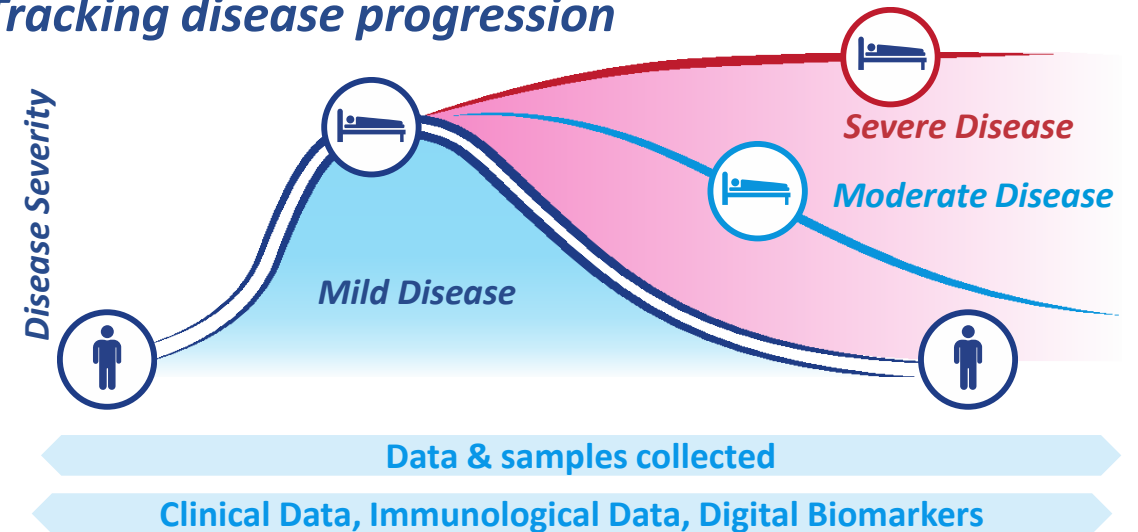
Ground breaking innovation 	First time human challenge data analysed using AI 
Prioritise drugs with existing Phase I safety data – reducing spend and risk 	Identify drugs that are more likely to succeed 

Influenza

- Deal signed with CytoReason – March 22
- To identify new drug targets
- CytoReason work with 5/10 top global pharma including Pfizer, Roche, Sanofi
- **Outputs expected in H1 2023**



Tracking disease progression



RSV

- Deal signed with OneThree Biotech Inc – Feb 22
- Identify new drug targets & treatments
- **Outputs expected in H2 2022**



Key Upcoming Milestones & Opportunities

Multiple value inflection points in 2022 & beyond

POLB 001

LPS challenge study to commence June 2022

Data expected before year end 2022 – monetisation commences

POLB 002

Development plan underway

POLB 003

Complete in-licence & evaluation of 5 other vaccine programs

Oral Vaccine Delivery Platform - Development plan underway

RSV AI Drug Programme - Outputs expected in H2 2022

Influenza AI Drug Programme - Outputs expected in H1 2023

Non-dilutive funding - Applications progressing

IP Portfolio - Continuing to expand & strengthen



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Questions?



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Poolbeg Pharma



Appendix



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Poolbeg Pharma

Experienced Leadership Team



Cathal Friel
Chairman

- Co-founder & Chairman of Open Orphan plc
- Co-founder & shareholder in Amryt Pharma plc; leading London & Nasdaq orphan drug company
- Established Raglan Capital in 2007
- Founder & Chairman of Fastnet Oil & Gas plc which IPO'ed 2012
- Co-founder of Merrion Stockbrokers in Dublin in 2001



Jeremy Skillington
CEO

- 19 years global industry experience: US, UK, Germany & Ireland
- BD & employee #3 at Inflazome. Sold to Roche in 2020, €380M + milestones; significant ROI to investors. Developing treatments for inflammatory diseases
- BD at Genentech (USA), Ethris (Germany). Co-founded & CEO of TriMod Therapeutics
- PhD in Biochemistry NUI Galway & Post-Doc at UC San Francisco



Ian O'Connell
CFO

- Financial professional with healthcare & public markets experience
- Co-founder, VP Corp Dev & Board Observer at Open Orphan - led acquisition of hVIVO plc & RTO of Venn plc
- Worked with Cathal Friel & Amryt's senior management to establish Amryt Pharma plc
- Corporate finance at both Raglan Capital & Deloitte
- Member of Chartered Accountants Ireland



Carol Dalton
VP IR & PR

- Co-founder & VP Investor Relations & Public Relations at Open Orphan plc & Poolbeg Pharma plc
- Managed multiple funding rounds of in excess of £47m
- Managed & maximised Open Orphan's worldwide media coverage in 2020
- Senior Associate at Raglan Capital
- BSc in Nutraceuticals with a focus on antimicrobial resistance



Patrick Ashe
Non-Executive Director

- >30 years of experience in pharma & biotech
- BD at **Elan** plc for 16 years
- Co-founder and BD lead at Athpharma, AGI Therapeutics & Vidara
- BD at Horizon Therapeutics following acquisition of Vidara



Prof Luke O'Neill
Non-Executive Director

- Co-Founded Inflazome which was acquired by Roche in 2020 for €380m + milestones
- World-renowned immunologist & Chair of Biochemistry in the School of Biochemistry & Immunology at Trinity College Dublin
- Fellow, Royal Society & Royal Irish Academy Gold Medal for Life Science



Eddie Gibson
Non-Executive Director

- 24 years' experience leading biopharma organisations
- Led many major European launches and creation & implementation of global access plans many therapy areas including virology
- Founder of Wickenstones, pharma market access consultancy



Experienced Team to Execute

Additional team members



CMO

- Industry leading CMO
- Expert in designing and implementing clinical trials
- Over 20 years experience in pharma & biotech with drug development focus
- Clinically experienced medical doctor
- Previously CMO for North American Nasdaq listed biotech company



Liam Tremble

Clinical Operations Project Manager

- BSc honours degree in Immunology, Masters in Translational Biology
- PhD on the role of the immune system in melanoma
- Joined hVIVO 2020, key strategist in Volunteer Delivery and Clinical Science Group departments



Alan Bell

Clinical Development Project Manager

- 14+ years experience in clinical development for Phase I-III drugs
- Published in inflammation pathway analysis, associated biomarkers
- Qualifications in Clinical Physiology, Respiratory Medicine, Human & Clinical Pharmacology



Ross Crockett

Financial Controller

- Extensive experience in senior finance positions in public listed companies incl. Amryt Pharma plc, Cove Energy plc, Fastnet Oil & Gas plc & Orogen Gold plc
- Member of Chartered Accountants Ireland



Initial Scientific Advisory Board Members



Elaine Sullivan, PhD

- CEO of Dargle Therapeutics & Executive Chairman of Keltic Pharma
- 25 years of international experience working in Pharma and Biotech including as VP of Global External R&D at Eli Lilly
- Raised \$100m for Carrick Therapeutics as Founder
- NED at Open Orphan plc, IP Group plc, Active Biotech AB and Supervisory Board at Evotec AG



Prof Luke O' Neill

- Co-Founded Inflazome which was acquired by Roche for €380m in 2020
- World-renowned immunologist and Chair of Biochemistry in the School of Biochemistry and Immunology at Trinity College Dublin
- Fellow, Royal Society & Royal Irish Academy Gold Medal for Life Science



Daniel F. Hoft, MD, PhD

- Director of the Division of Infectious Diseases, Allergy & Immunology at Saint Louis University (SLU) School of Medicine
- Principal Investigator of SLU's Vaccine & Treatment Evaluation Unit, one of nine NIH centres
- 32 years experience in immunology and infectious disease



Booming Infectious Disease Market

Vaccines, Therapeutics, Diagnostics

Market expected to exceed \$250bn by 2025
Big Pharma seeking products



2021 forecast: COVID-19 brings infectious disease R&D out of the wilderness Dec 22, 2020

Forbes

Dec 19, 2021

Flu Vaccine Mismatch Raises Further Concerns About 'Twindemic' With Covid-19



United Nations

UN News

Global perspective Human stories

Infectious diseases 'clear and present danger' everywhere

27 December 2021

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September 7, 2021 07:12 AM EDT Updated 9 hours ago | Pharma, Coronavirus



White House seeks \$65B to prepare for future pandemics in 'Apollo'-like effort

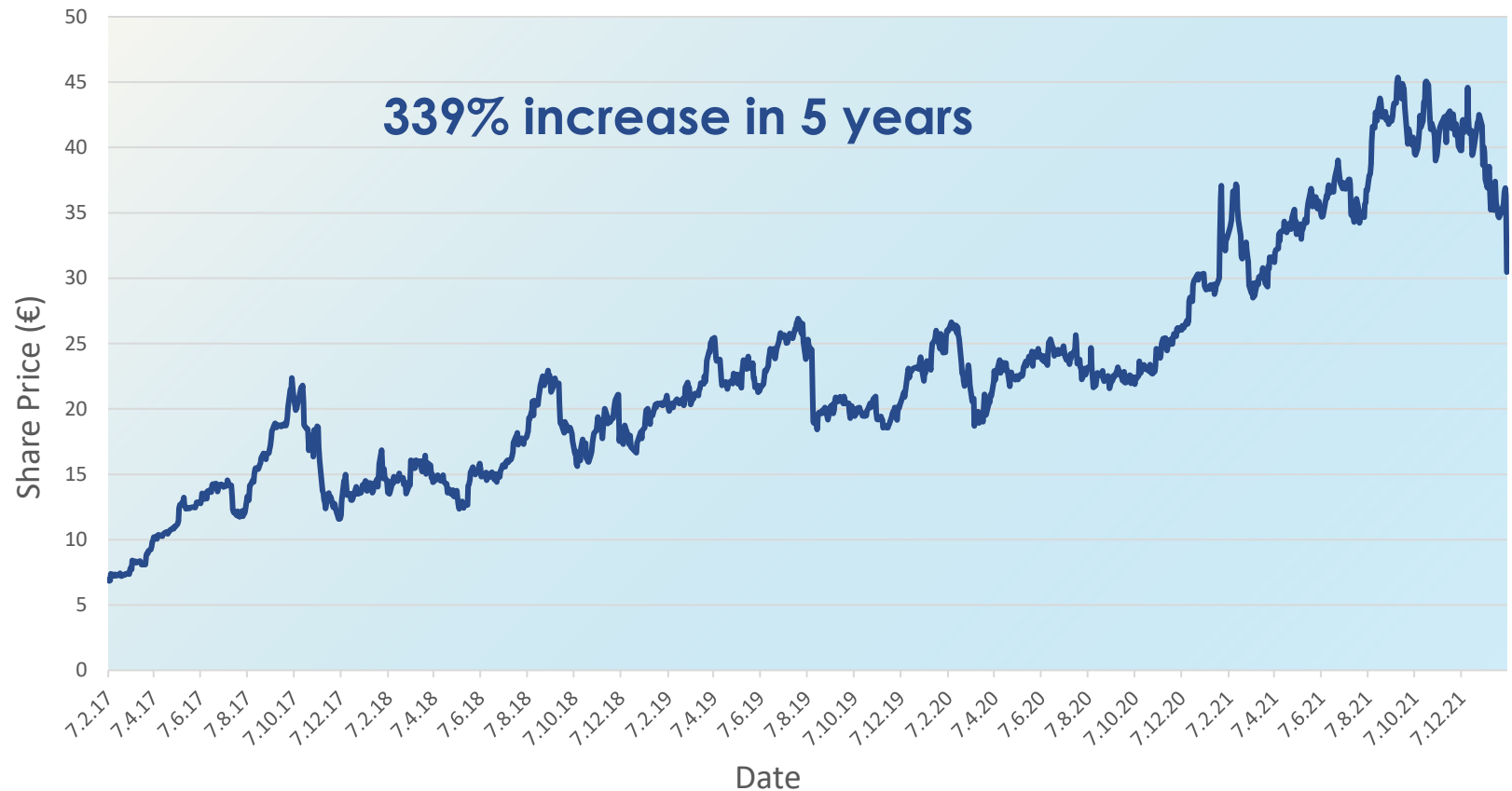
Capital Light & Early Monetisation Model

A model that works



The only other company in the space following a similar model to Poolbeg

- Roots as a CRO, brings assets through Phase I & II
- Out-licence / partner with Big Pharma for significant upfronts + milestones + royalties



Evotec licence to Takeda

Significant upfront + \$160m milestones per product + royalties, March 2021

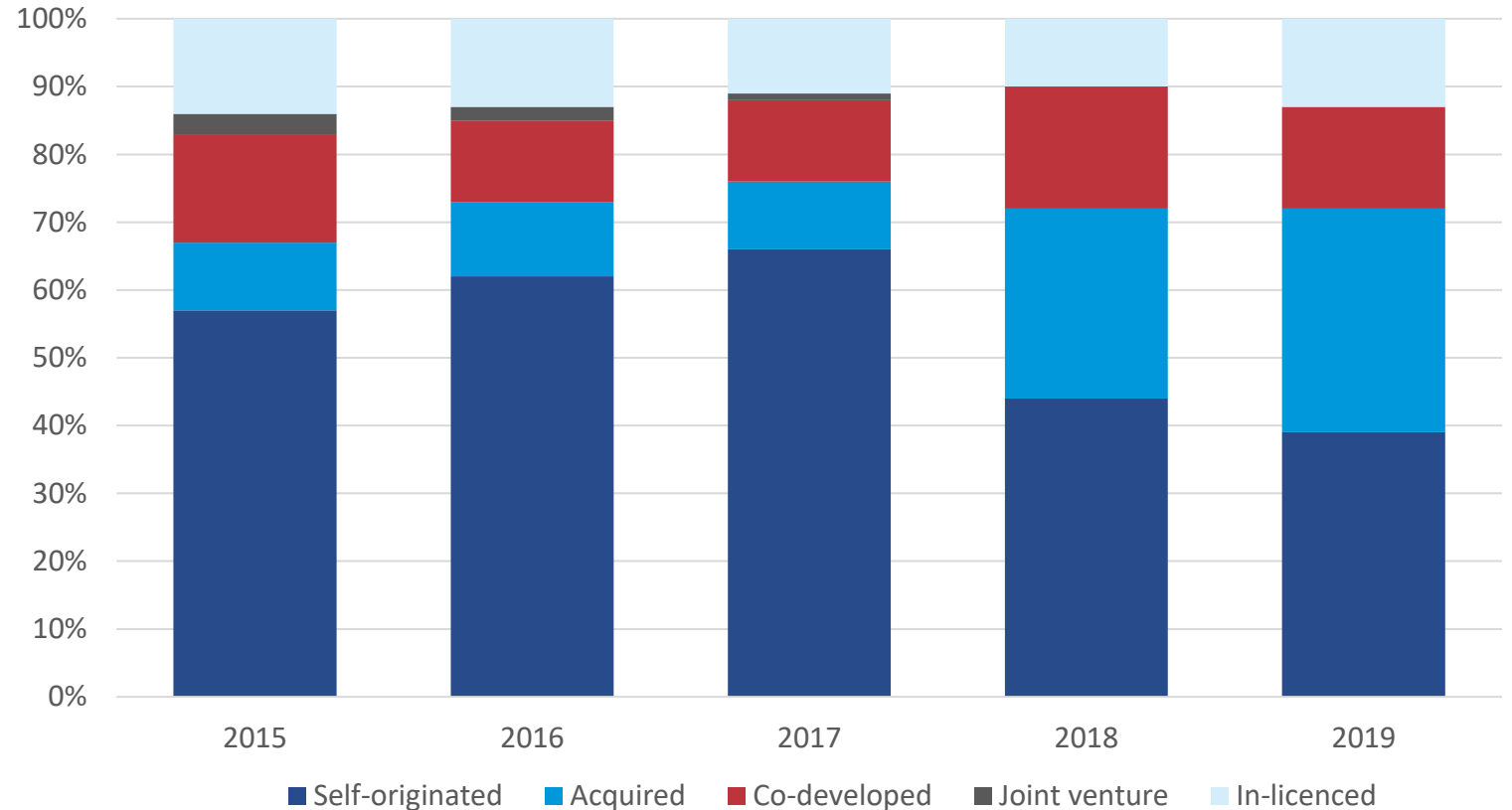
RNA targeting

Capital Light & Early Monetisation Model

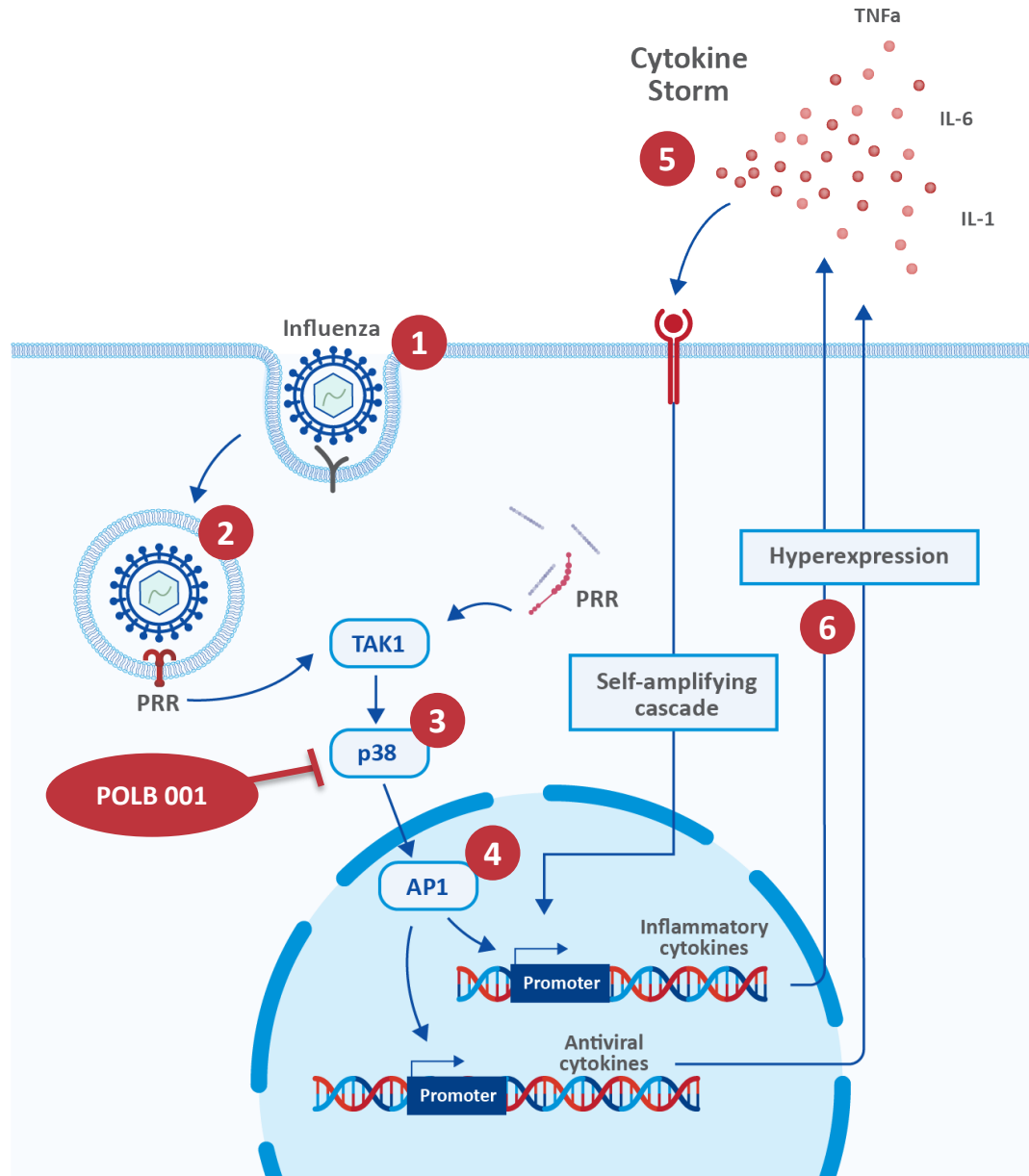
Big Pharma are looking to in-licence infectious disease products

More deals, less in house development

The trend for sourcing clinical candidates via in-licensing, acquisition or co-development is continuing to expand



POLB 001 – Mechanism of Action



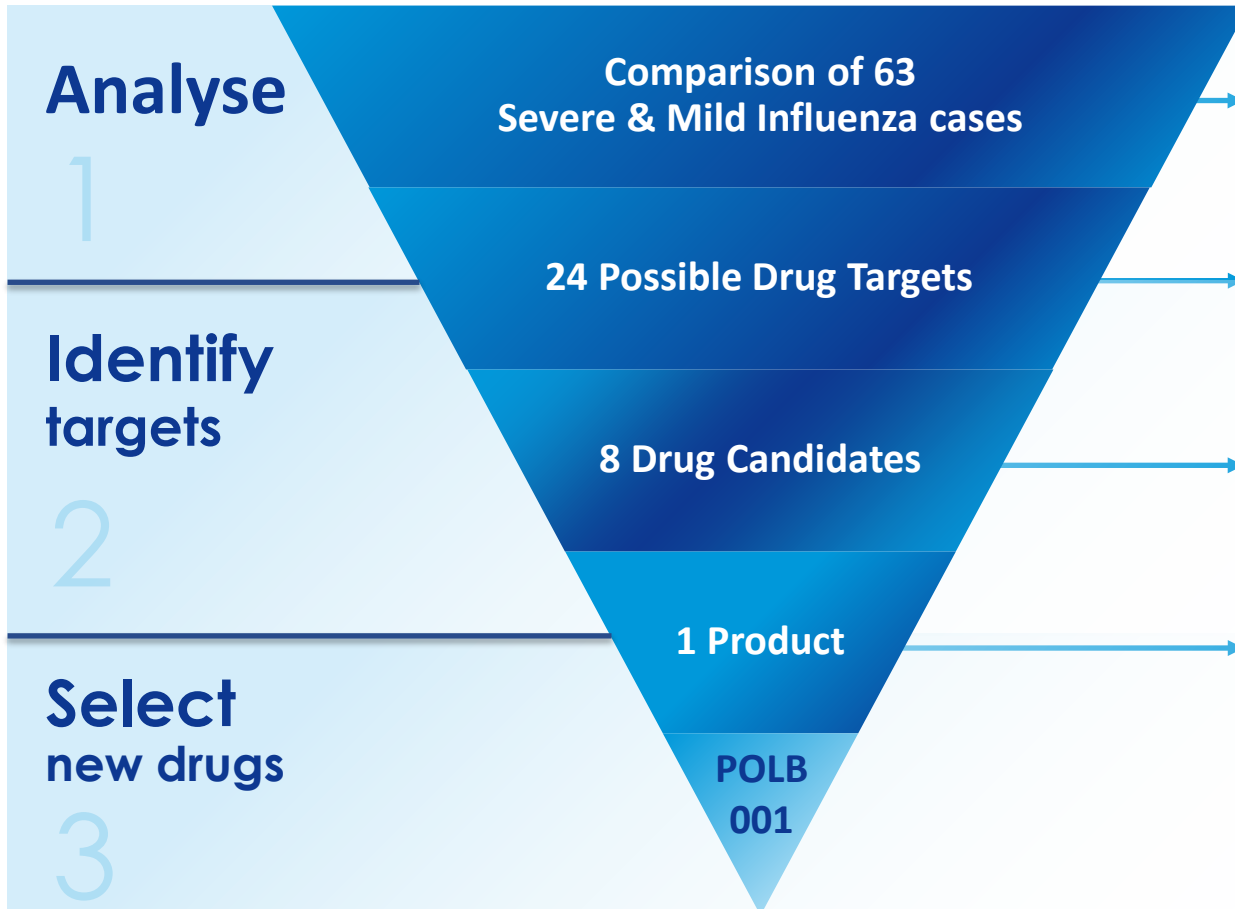
- 1 Influenza virus infects cells of the respiratory tract
- 2 Pattern recognition receptors are activated by endosomal and cytoplasmic viral antigens
- 3 A signalling cascade involving p38 MAP Kinase results in activation of DNA promoters regulating the expression of inflammatory and antiviral cytokines
- 4 A high viral burden can activate hyperexpression of cytokines
- 5 Inflammatory cytokines act to self-amplify expression
- 6 A positive feedback loop results in a cytokine storm, also known as hypercytokinaemia that can cause severe tissue damage including ALI and ARDS

POLB 001 – Ideally Suited as a Severe Influenza Therapeutic

What is p38 MAP Kinase?

- **Central role in regulation of pro-inflammatory signalling** networks, cytokine synthesis in immune cells, and inflammatory diseases¹
- **Responsive to stress stimuli**² such as inflammatory cytokines
- **Inhibition shown to effectively alleviate inflammatory diseases**³ (e.g. arthritis)
- Our data shows an unexplored relationship between p38 MAP Kinase and pathogenic immune responses associated with severe Influenza, that has the potential to reduce adverse outcomes

hVIVO's Unique Data & Samples Identified POLB 001



- Samples taken from patients with severe Influenza were compared against human challenge study subjects with 'mild' Influenza
- This work identified 24 potential molecules that play a role in Influenza severity, with p38 MAPK being the most important
- 40 p38 MAPK inhibitors were identified, and 8 were short-listed for detailed analysis
- Based on its superior performance and advantageous licensing terms, POLB 001 was chosen as the best candidate to take forward

Poolbeg Pharma's potential integration of **Artificial Intelligence ('AI')** into our licenced databanks will accelerate and provide additional power to this discovery tool

Vast Array of Human Challenge Study Data & Samples ready to mine using AI

300,000 individual samples stored at -80°C in 22 freezers



Flu, RSV, HRV,
Malaria,
SARS-CoV-2



Analyze samples to uncover common protective pathways

1

Identify pathways with clinical utility

2

Select new drugs & drugs that can be repositioned quickly for new treatments

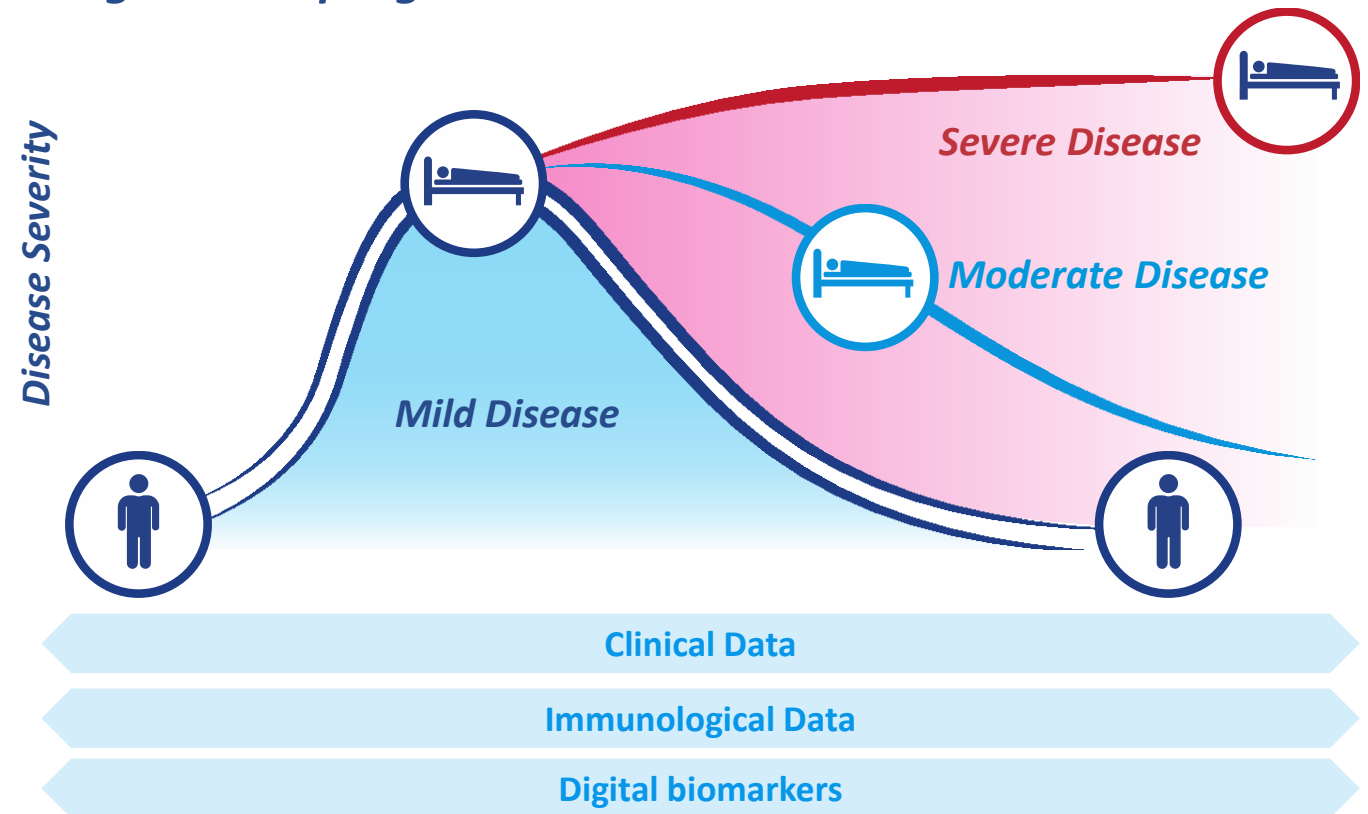
3

Human Challenge Data

Human Challenge Study: healthy volunteers are exposed to an infectious agent in a quarantine setting to assess the efficacy of vaccines or treatments

- hVIVO is a world-leader
- **Unique data (Day -1)** from human challenge studies **cannot be collected in a normal field trial**
- Data is **ideally suited to identify drug targets** with clinical utility:
 - Known dose of virus and time of infection
 - Clean, multi-parametric data from pre-infection through to post recovery
 - We can apply to **Flu, hRV, RSV, SARS-CoV-2 and Malaria**

Tracking disease progression



AI Drug Development

The human challenge model

The controlled nature of the quarantine environment means it is ideally suited for the identification of biomarkers due a number of factors



**Known infection
time & dose**



**Clean data – Maximised
signal, Minimized noise**



**Verifiable clinical
assessment**



**PCR and cell
culture virology**



**Serum protein
biomarkers**



**Tri-daily symptom
scores**



**Peripheral blood
transcriptomics**

	Standard Human Challenge Trial Data		
Baseline	Demographics	Height, Weight, BMI	Concomitant Medicines
Screening	Complete Physical Exam	Lung Function	Existing Antibody Levels
	Vital Signs	12 Lead ECG	Medical History
Trial	Biochemistry	Adverse Events	Safety Bloods
	Symptoms	12 Lead ECG	Bi-daily Viral Burden
Follow Up	Urinalysis	Symptoms	Safety Bloods

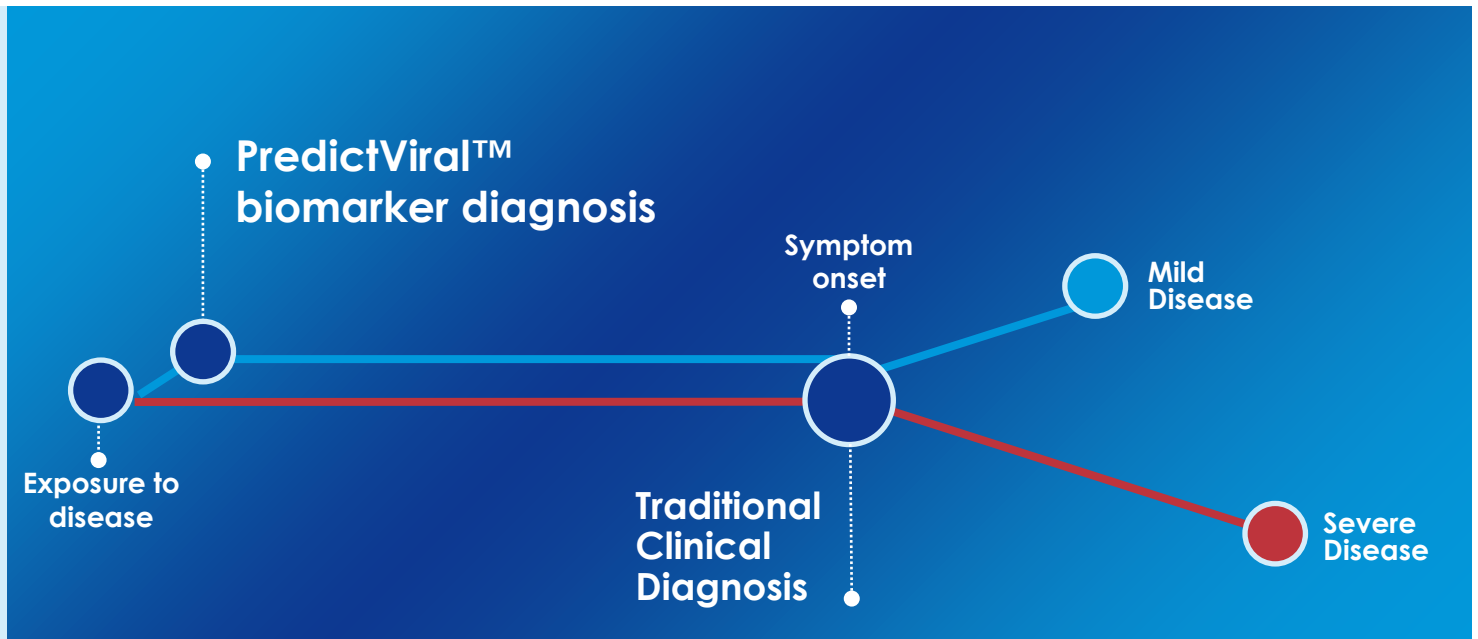
PredictViral™ Biomarker Platform for Predicting Severe Disease

Potential to transform the way infectious diseases are treated, opportunity to licence this tool to Big Pharma
Further patent applications submitted – October 2021

PredictViral™ Biomarker Diagnostics vs Traditional Diagnosis of Disease

Advantages

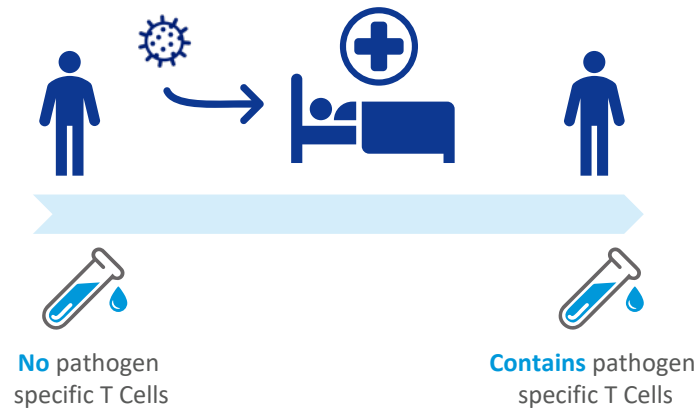
- ✓ Identify severe disease before it is symptomatically visible
- ✓ Triage patients based on predicted disease severity
- ✓ Increases window for effective treatment where early intervention is crucial, e.g. Influenza. i.e. 48hr window of efficacy for many antivirals



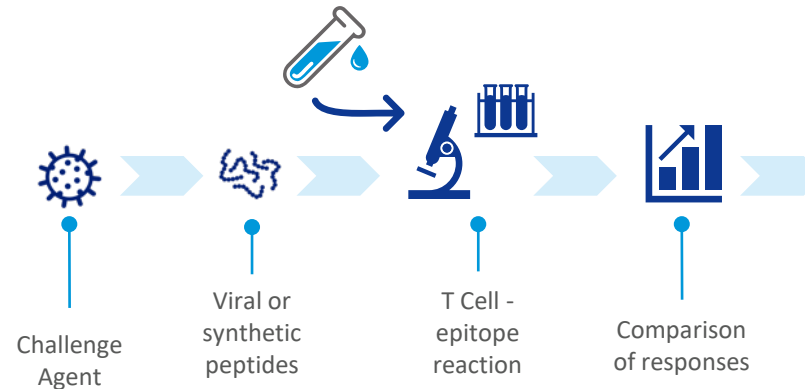
Unique Vaccine Discovery Platform

Harnessing the human challenge model to discover new vaccines

Step 1. T Cell Generation



Step 2. Vaccine Discovery



What is an Epitope?

- Part of a pathogen that the immune system recognises
- It is the smallest unit of a molecule required to engage the immune system
- Effective vaccines require effective epitopes

Identification of epitopes that can generate robust immunity

Significant value in vaccine design and discovery platforms



Mkt Cap c. \$6.5bn



Mkt Cap c. \$72bn



Mkt Cap c\$789m



Mkt Cap c. \$39bn

Why Reposition Drugs?

1 Leverage new, **novel** disease biology insights

2 Discovery & development phases already completed - **reducing spend**

3 Already licenced and trialled in patients - **increased probability of success**

4 Already proven to be safe, **existing clinical safety & efficacy data** to be utilised

Traditional drug discovery: 12-16 years¹

Drug repositioning: <6 years at a fraction of the cost



Poolbeg Pharma plc

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