

POOLBEG PHARMA

Company Presentation

July 2022

AIM: POLB
OTCQB: POLBF

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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

London STOCK EXCHANGE

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 $4.1bn market cap. Evotec also has deep roots in the clinical trials business

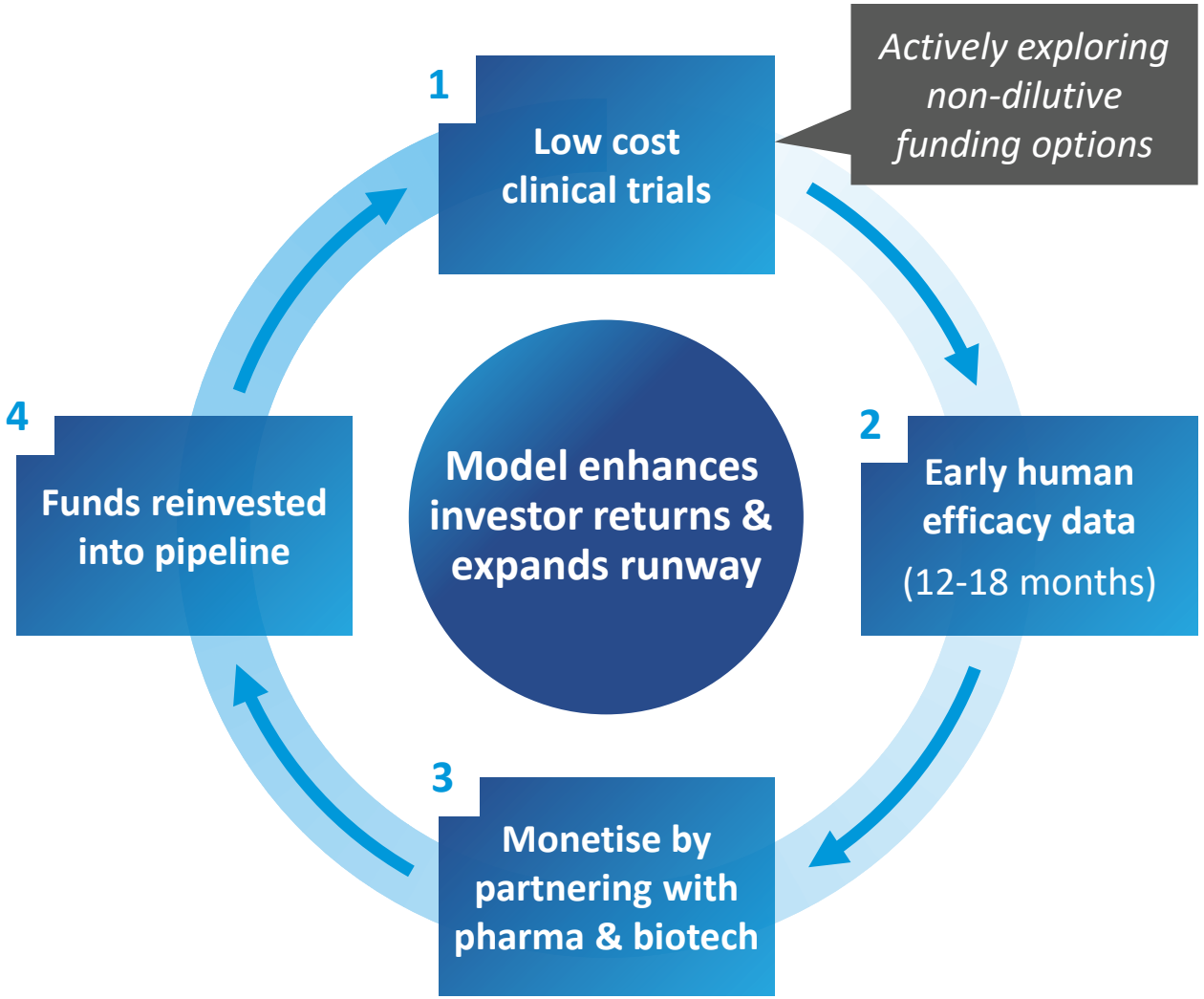
Targeting booming infectious disease market
Expected value >$250bn by 2025

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

- **Rapidly expanding portfolio of assets**
- **Self funding business model - out-licensing early and often**
- **Focus on European and N. American rights - can sell Asian & other market rights for cash**
- **Becoming a one-stop-shop for big pharma and biotechs seeking infectious disease assets**

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 (Phase II)

Pfizer acquired ReViral
up to $525m, April 2022
Respiratory Syncytial Virus (RSV) (Preclinical – Phase II assets)

Merck acquired OncoImmune
$425m upfront, Nov 2020
COVID-19 (Phase III)

Pfizer's Valneva deal
$130m upfront + $188m follow-on, April 2020
Lyme Disease (Phase II)

Bav Nordic licence Chinese rights to Nuance Pharma
$12.5m upfront + $200m follow-on, Mar 2022
Respiratory Syncytial Virus (RSV) (Phase III ready)

The Year in Review – 12 months since IPO

Executing on our strategy – momentum continuing to build

POLB 001

LPS challenge trial commencement imminent

Data expected by year end with monetisation to rapidly commence thereafter

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

2 Artificial Intelligence deals signed

Identify new drug targets & treatments for RSV & Influenza

Commenced trading on US OTCQB market

March 2022

Well capitalised with a strong cash balance of £20.9m at 31 Dec 2021

Low cash burn & significant financial resources to support growing pipeline

Exploring non-dilutive grant funding

Expanding Pipeline of Assets

Product pipeline

Product Candidate	Program	PreClinical	Phase 1	Phase 2	Phase 3
POLB 001	Severe Influenza treatment	LPS trial data expected Q4 '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

CytoReason

Outputs - H1 2023

Artificial Intelligence Drug Discovery Programme

Respiratory Syncytial Virus

ONETHREE BIOTECH

Outputs - H2 2022

Oral Vaccine Delivery Platform

Developing vaccines for multiple indications

AnaBio™ Technologies

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

Pre-IPO Post-IPO

*Reviewing 5 additional bacterial vaccine candidates from UCD

POLB 001 – Severe Influenza Treatment

Clinical stage potential blockbuster immunomodulator

Potential transformational treatment

- Positive Phase I studies completed
  - Safe & well tolerated
- Agnostic to viral strain
- Shelf-stable oral drug
  - Ideal for stockpiling

Worldwide rights for all uses in humans

- Patent protected until 2038
- Expanding IP
- Exploring further disease indications = increase value

How does it work?

- Flu virus activates the inflammatory immune pathway, p38 MAP Kinase
- In severe flu p38 is over-activated causing a potentially deadly cytokine storm
- POLB 001 blocks p38 stopping the tissue damaged caused by the cytokine storm

Large addressable market

- Potential peak sales $275m+ in influenza alone in Europe & US
- No suitable drug on the market

Mid 2022
- Start of LPS challenge trial

Q4 2022
- Early human efficacy data expected

- Plan for early monetisation thereafter

POLB 001 – Successful Phase I study already completed

Safety and tolerability demonstrated – rapid progression to challenge study

Phase 1 Key Outcomes

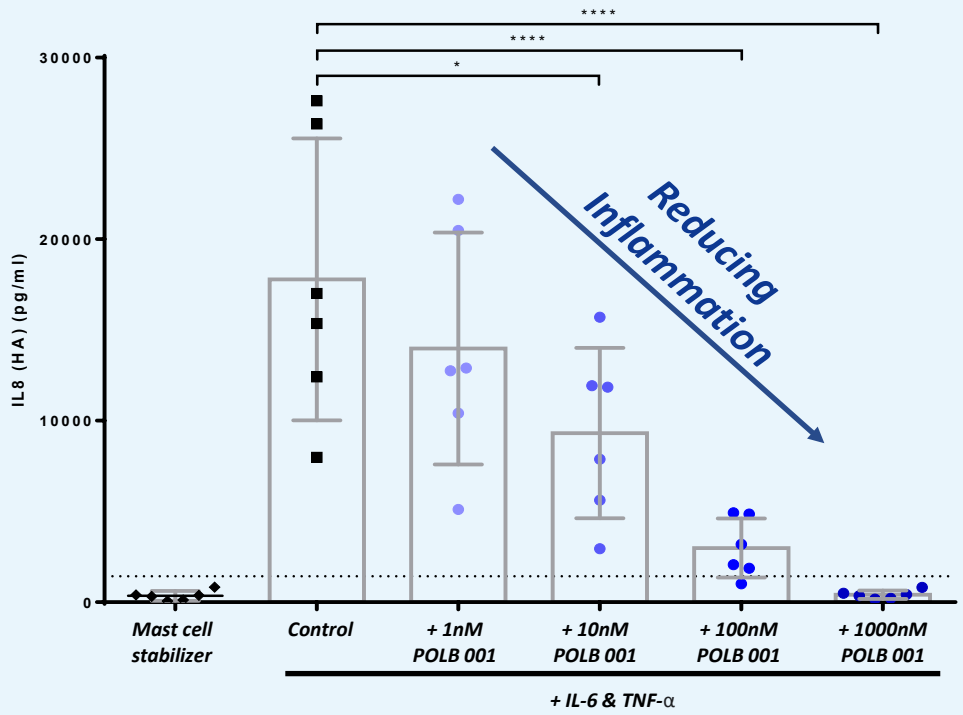
Predictable and durable response
Data collected in this study demonstrate that POLB 001 administration produces a potent and long-lasting inhibition of p38 MAP-kinase activity in humans

Safe and well-tolerated
After administration of single doses up to 600 mg and repeated doses up to 150 mg, there were neither serious nor limiting adverse events to POLB 001

LPS Ex-Vivo
At a 150mg twice daily dose, an inhibition of LPS-induced TNF-a between 70 & 90% was achieved

Eliminated class-associated tox issues
Short-term use of p38 for acute inflammation overcomes tox concerns associated with long-term treatment with p38 inhibitors for chronic inflammatory conditions (e.g. Arthritis)

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.

Source: Moerland, M., Kales, A. J., Broekhuizen, K., Nässander, U., Nelissen, R., Kam, M. L., Peeters, P. A., & Burggraaf, J. (2020). Proof of pharmacology of Org 48775-0, a p38 MAP kinase inhibitor, in healthy volunteers. British Journal of Clinical Pharmacology, 87(5), 2321–2332. https://doi.org/10.1111/bcp.14655

POLB 001 – p38 inhibitor for severe influenza

The challenge trial will use LPS as a surrogate for severe influenza to evaluate the efficacy of POLB 001

LPS Trial Objective: To evaluate the effect of POLB 001 on inflammatory responses following an intradermal and an intravenous LPS challenge in healthy volunteers

Trial Design

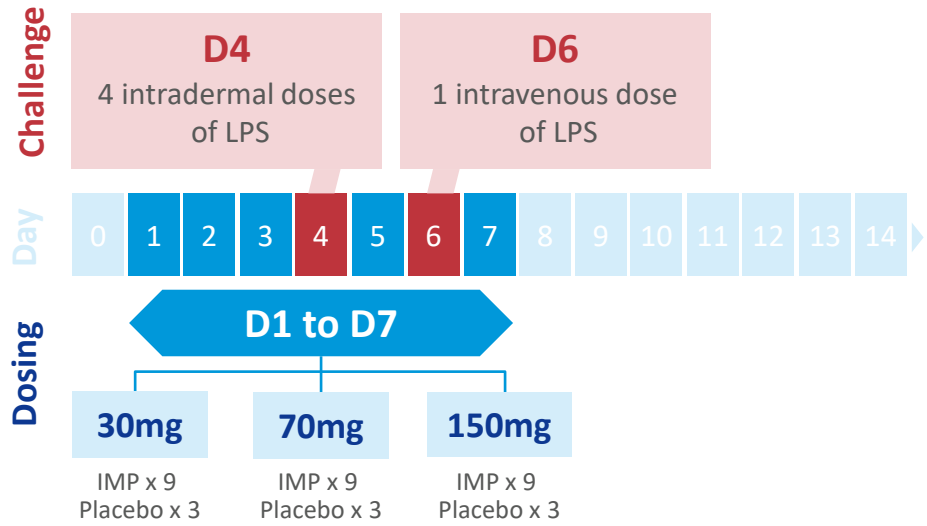
- A randomized, double-blind, placebo-controlled, multiple dose, inflammatory challenge trial in healthy volunteers
- Three cohorts with escalating dose, 12 volunteers per cohort
- POLB 001 or placebo dosed orally, twice daily for 7 consecutive days

1. Patient Profile

Healthy volunteers without a history of inflammatory diseases, anti-inflammatory medicines use or other inflammatory complications

CHDR
Centre for Human Drug Research

2. Trial design



3. Endpoints

Intradermal LPS challenge

- Skin response by imaging
- Blister exudate analysis
- Skin punch biopsy
- Safety & tolerability

Intravenous LPS challenge

- Bloods (cytokines, vascular markers, CRP)
- *Ex-vivo* LPS response
- Safety & tolerability (inc. vital signs, AE's, ECG, Haematology)

POLB 002 - A global need for respiratory virus infection products

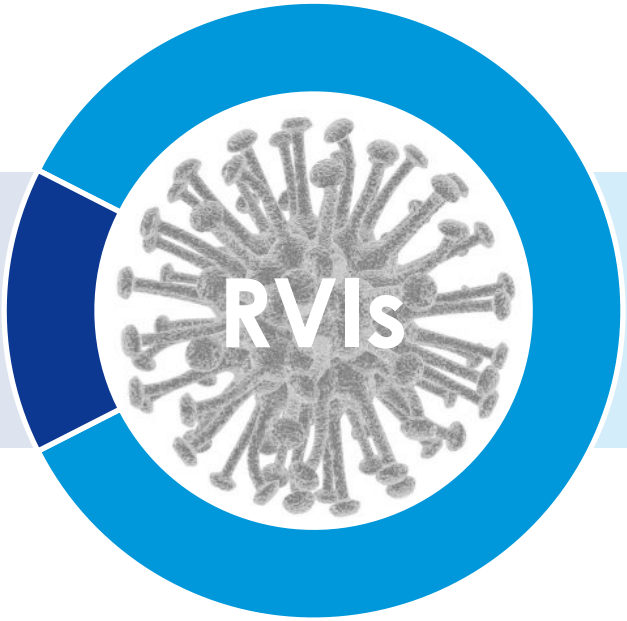
Most respiratory virus infections cannot be treated

15%

INFLUENZA

VACCINES
Protection variable

ANTI-VIRAL THERAPIES
Require diagnosis of virus type



85%

NON-INFLUENZA RVIs

FEW AVAILABLE TREATMENTS

"A broad spectrum antiviral that gets around the fact that we don't always know what we are treating would be game changing"

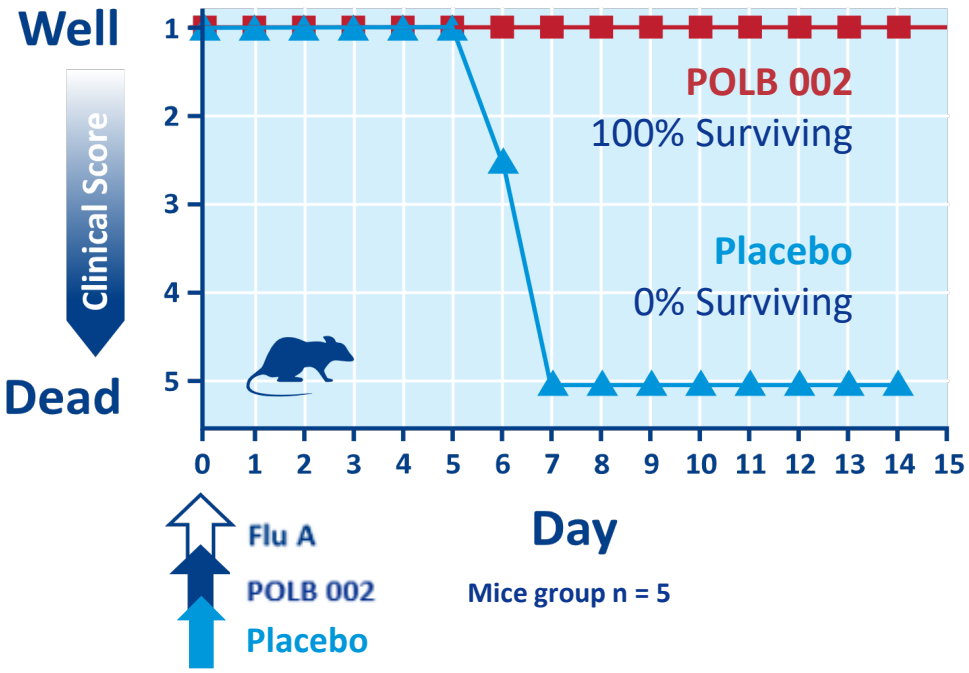
US Key Opinion Leader

POLB 002 - Respiratory Virus Infection Immunotherapy

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

- Single dose, intranasal, dual action prophylactic & therapeutic
  - Triggers nasal cells into an antiviral state to protect against the virus
  - Blocks the virus from replicating
- Late preclinical stage with extensive preclinical data package
  - No reduction in efficacy or safety issues after repeat dosing
- US & European patents granted & continuing to expand

In-vivo Influenza A challenge



Respiratory Virus Infections

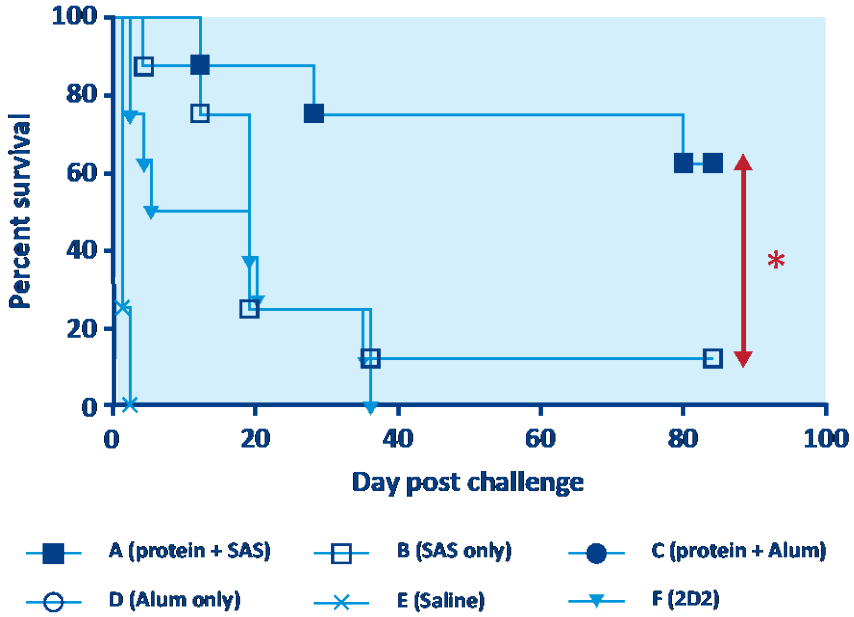
5-20% global population infected by seasonal outbreaks	**3M+** annual deaths worldwide	**Top 5** global cause of death	**Pandemic Potential**

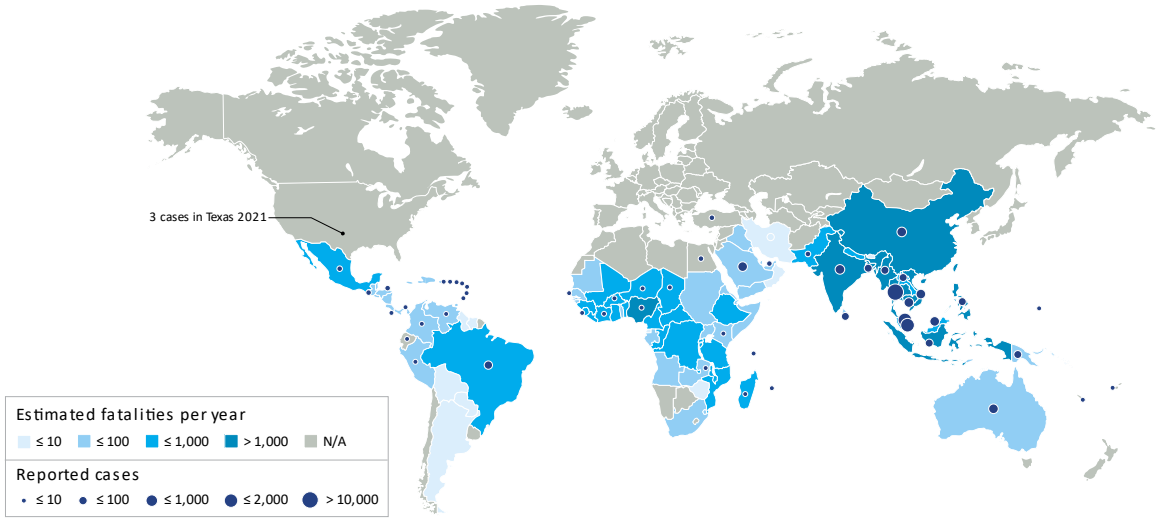
POLB 003 – Melioidosis Vaccine

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 biothreat
- Antibiotic resistant
- Under the agreement with UCD, 5 other vaccine programs are also being evaluated

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





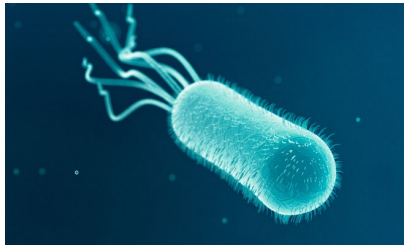
165,000
estimated cases per annum

54%
of cases are fatal

0
vaccines available

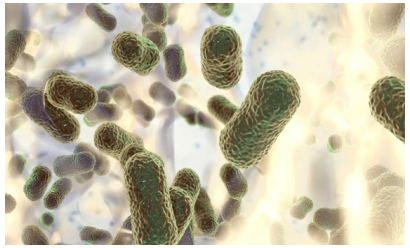
Additional vaccine candidates from UCD

Option agreement for 5 additional vaccine antigen candidates



O157 E.coli/STEC/ VTEC

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



Acinetobacter baumannii

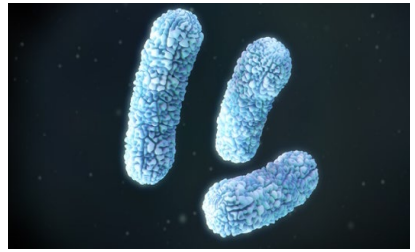
- Multiple antigens identified
- Prevalent issue in US Defence and healthcare settings, resulting in burdensome management of complications

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



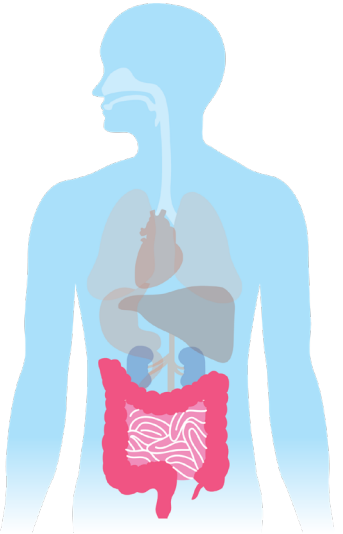
Burkholderia cepacia complex

- 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
- Highly attractive market
- Multiple disease indications



Oral vaccines reduce manufacturing challenges, enhance vaccine uptake & can create mucosal immunity

Mass Vaccination
Pandemic has shown injections cannot give global protection

No needles
Needle phobia has been shown to reduce vaccine uptake

Easy Administration
Healthcare staff not needed

Antigenic Drift
Prime boost approaches can give cross antigen specificity

Vaccine Hesitancy
People are more willing to take an oral product

Cold Chain
Easy distribution and enhanced stability profile

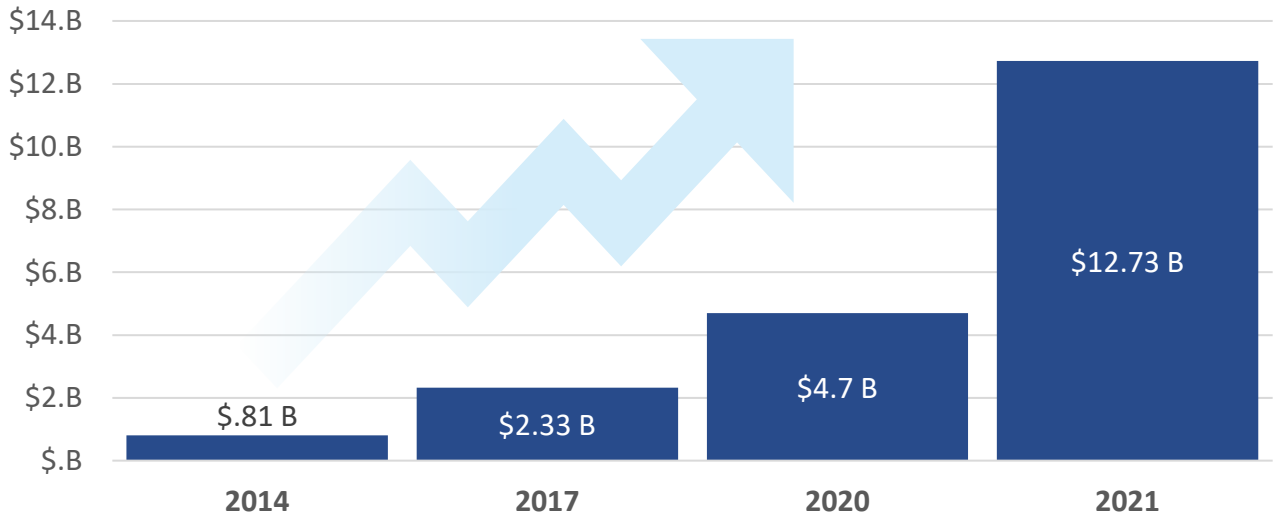
Artificial Intelligence – revolutionising drug discovery

Pharmaceutical AI business is "heating up"

50% of global healthcare companies will implement AI strategies by **2025**

Investment in AI increase of 400% 2020 vs 2021

Investment in pharmaceutical AI



AI-designed molecules have the potential to leapfrog traditionally developed drugs on their way toward human testing

FIERCE Biotech

Sanofi Joins AI Gold Rush in €4.6B Drug Discovery Pact with Exscientia LABIOTECH.eu
11/01/2022 -

FINANCIAL TIMES

Investors bet on AI start-ups to turbocharge drug development Hannah Kuchler and Clive Cookson in London JUNE 11 2022

Artificial Intelligence: A Road to Faster and Better Drug Discovery? 28/09/2021 - LABIOTECH.eu

Pharma News Intelligence
Deep Pharma Intelligence

Artificial Intelligence Drug Discovery Programme

Using AI to identify drug targets quicker & more cost effectively than previously possible

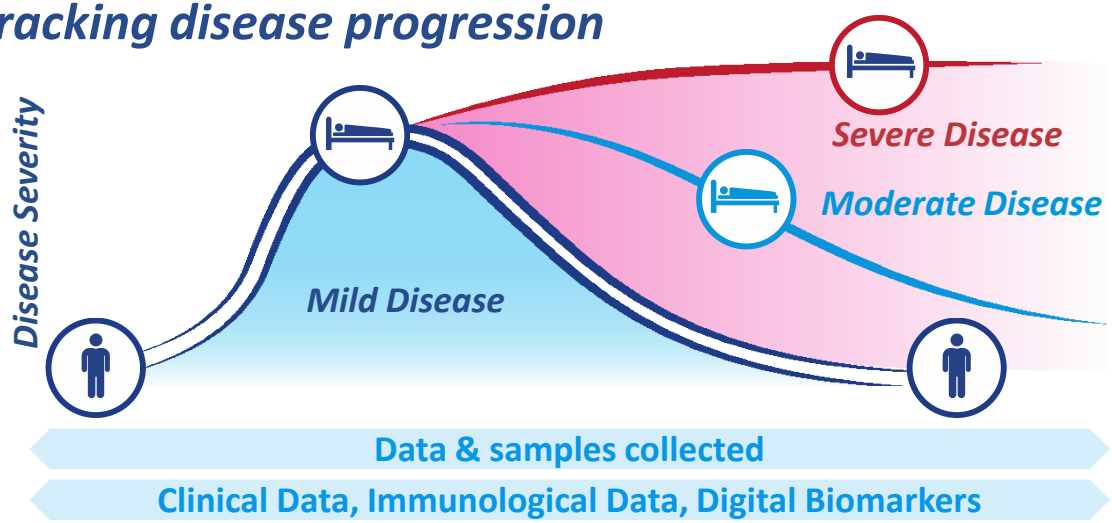
Ground breaking
innovation

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

Tracking disease progression



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**

CytoReason

RSV

- Deal signed with OneThree Biotech – Feb 22
- Identify new drug targets & treatments
- Stage 1 completed ✓
- **Outputs expected in H2 2022**

ONETHREE BIOTECH

*Directors belief

Key Upcoming Milestones & Opportunities

Multiple value inflection points in 2022 & beyond

POLB 001

LPS challenge trial commencement imminent

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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Appendix

AIM: POLB
OTCQB: POLBF

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

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Market expected to exceed $250bn by 2025

Big Pharma seeking products

FIERCE Biotech

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

Bill Gates says preventing next pandemic will cost $1 billion a year June 2022

CNN

There will be another pandemic, infectious disease experts say. June 2, 2022

ENDPOINTS NEWS

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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 – a model that works

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The only other company with a similar model:

evotec

- 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

Evotec collaborate with Novo Nordisk
Significant upfront + €150m development milestones per product + royalties + sales milestones, Aug 2020
Kidney Disease

Evotec collaborates with Pfizer
Significant upfront + development & sales milestones, Sept 2015
Fibrosis

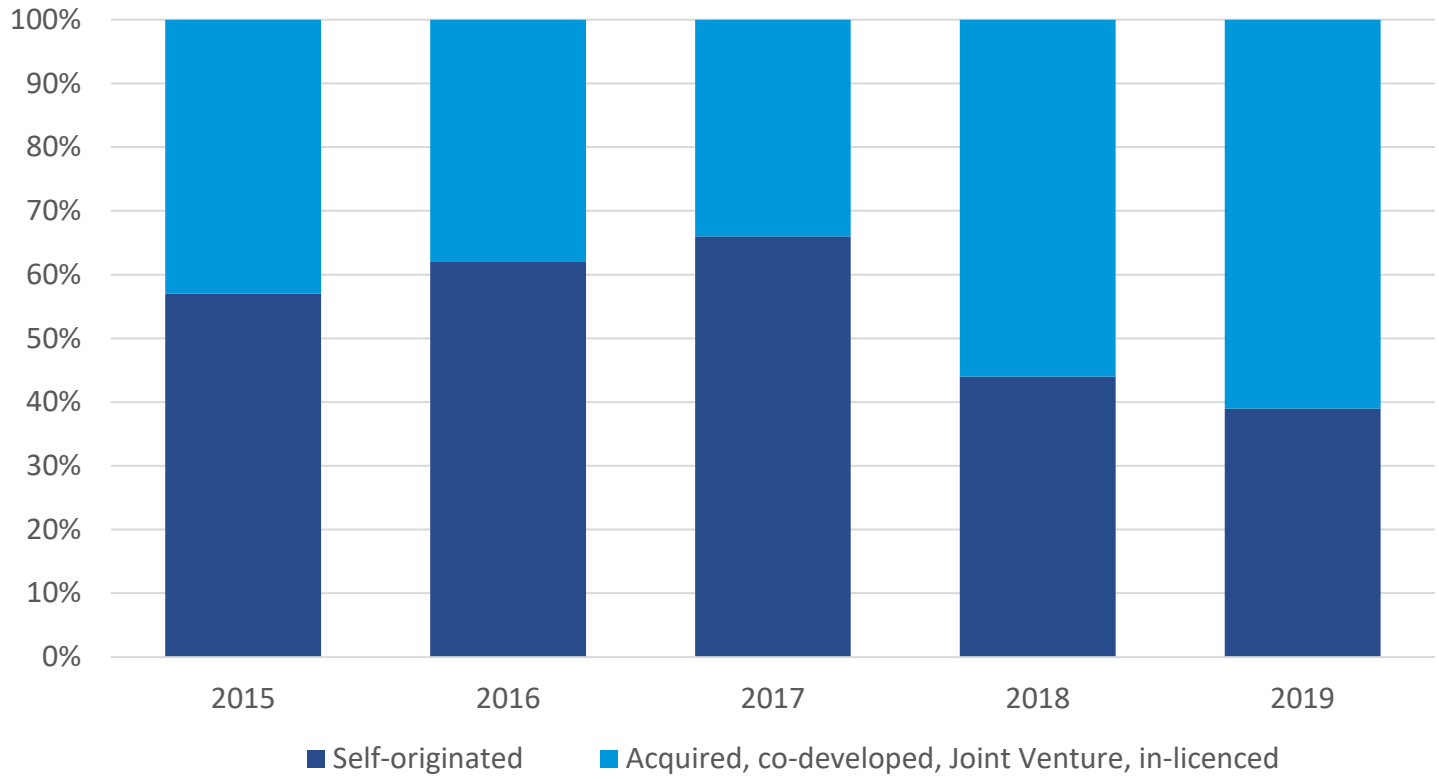
Capital Light & Early Monetisation Model

Big Pharma are looking to in-licence infectious disease products

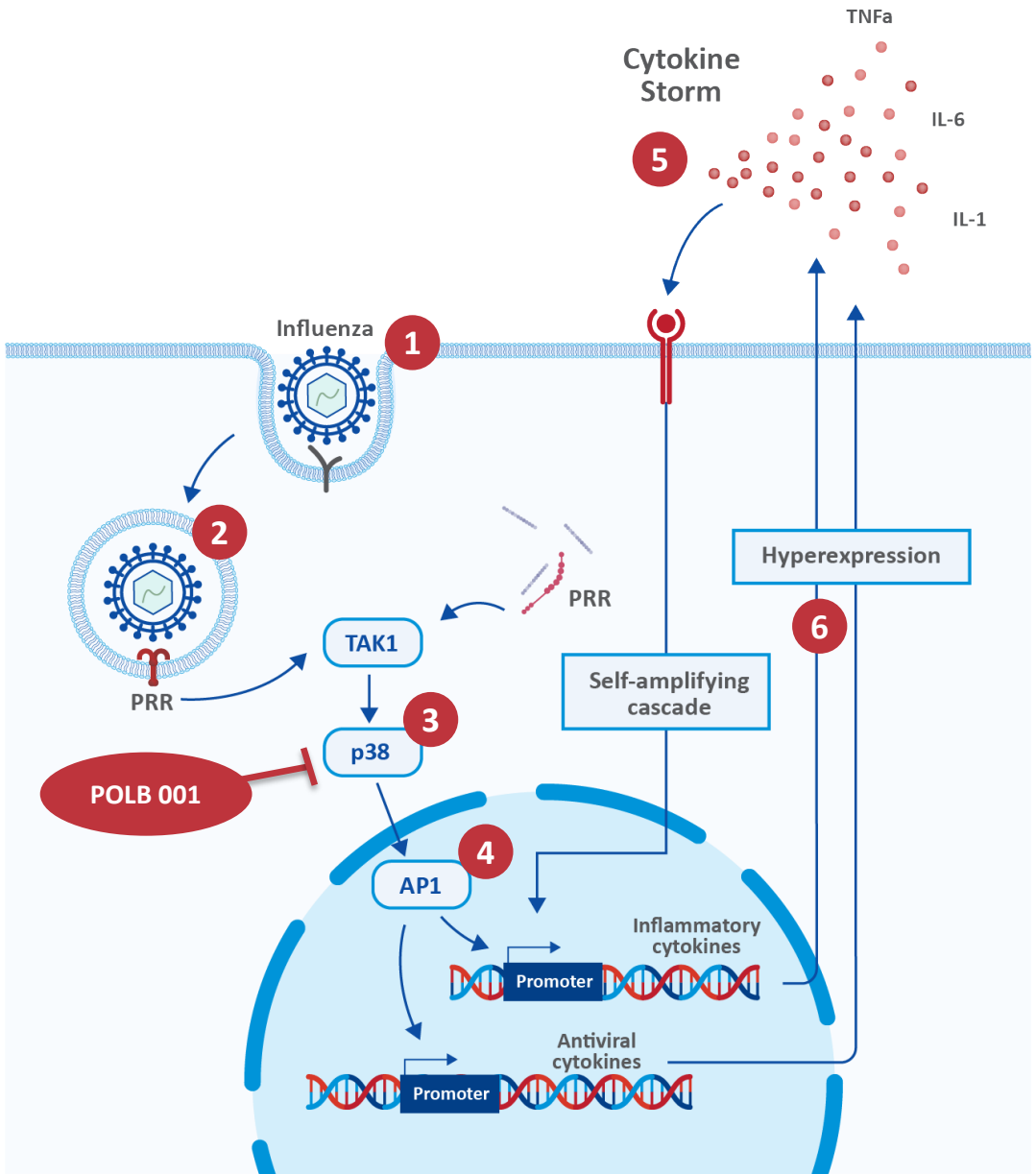
More deals, less in house development

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

Pharma developing less products in house



POLB 001 – Mechanism of Action

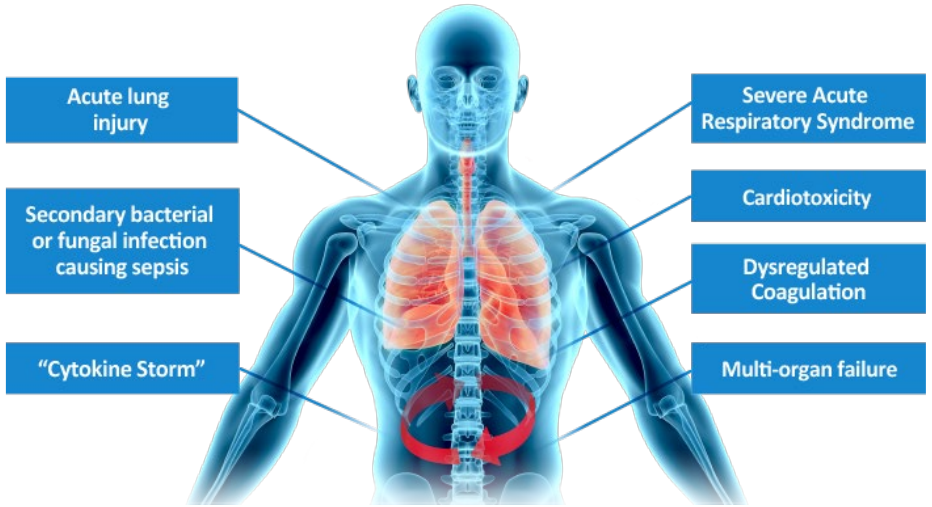


1. Influenza virus infects cells of the respiratory tract
2. Pattern recognition receptors are activated by endosomal and cytoplasmic viral antigens
3. A signalling cascade involving p38 MAP Kinase results in activation of DNA promoters regulating the expression of inflammatory and antiviral cytokines
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?

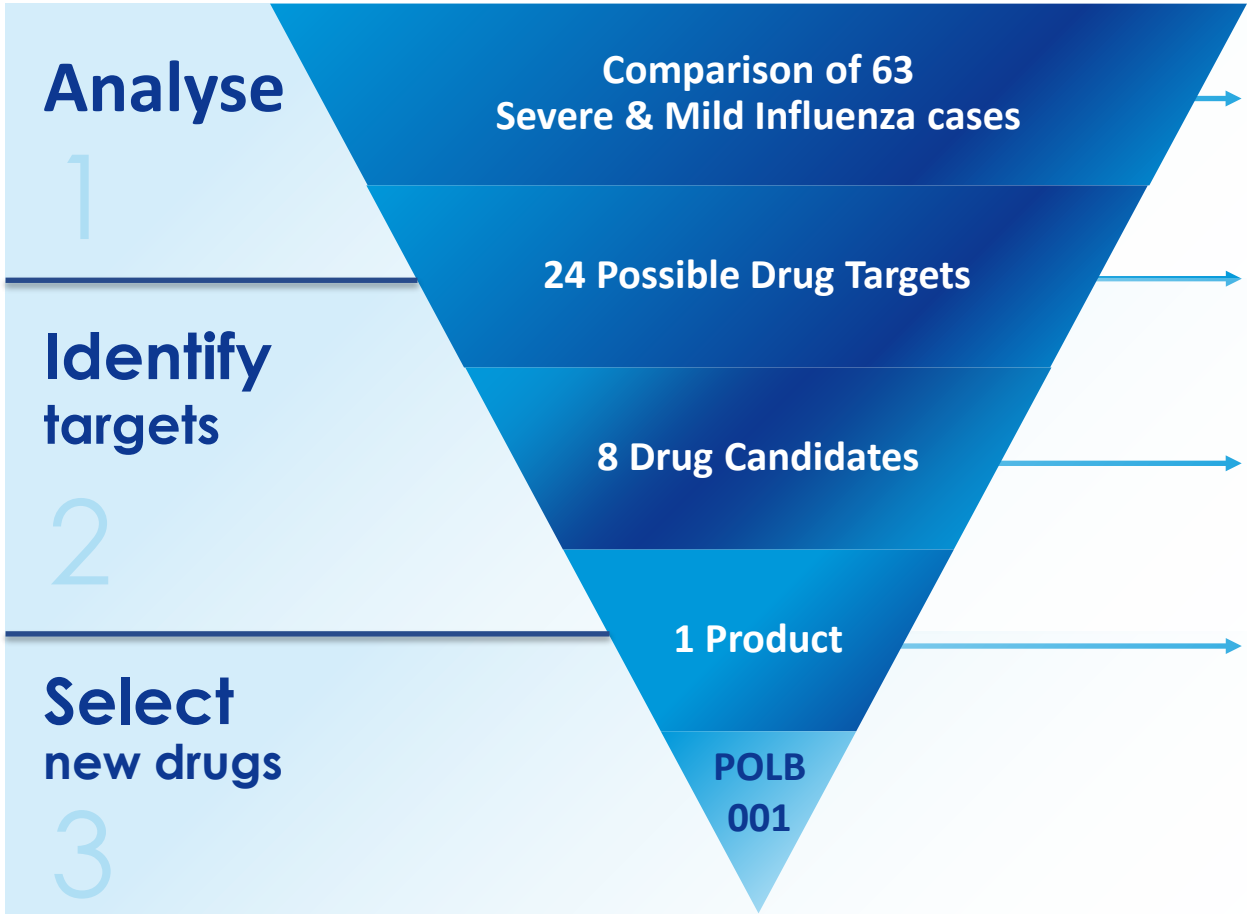
- **Central role in regulation of pro-inflammatory signalling** networks, cytokine synthesis in immune cells, and inflammatory diseases[1]
- **Responsive to stress stimuli**[2] such as inflammatory cytokines
- **Inhibition shown to effectively alleviate inflammatory diseases**[3] (e.g. arthritis)
- Our 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



Severe Influenza can cause life changing injuries

Source(s): [1] Wang et al, (1997). J. Biol. Chem. [2] Lee and Kim, (2017). Molecules. [3] Thalhamer et al, (2008). Rheumatology.

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

ViralPredict™ Biomarker Platform for Predicting Severe Disease

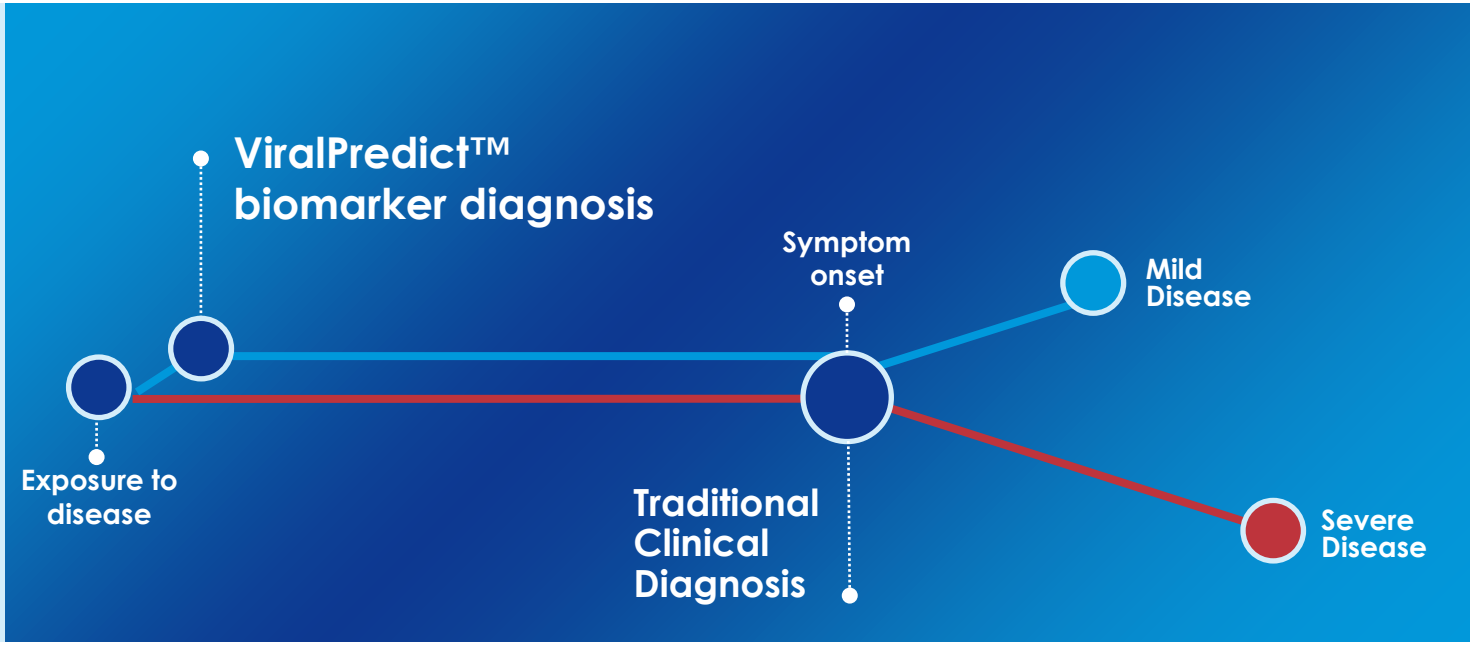
Potential to transform the way infectious diseases are treated, opportunity to licence this tool to Big Pharma

Further patent applications submitted – October 2021

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

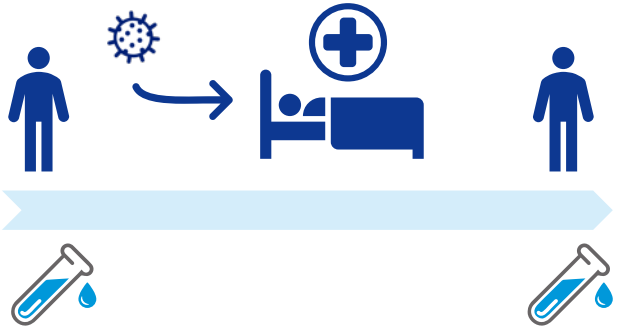
ViralPredict™ Biomarker Diagnostics vs Traditional Diagnosis of Disease



Unique Vaccine Discovery Platform

Harnessing the human challenge model to discover new vaccines

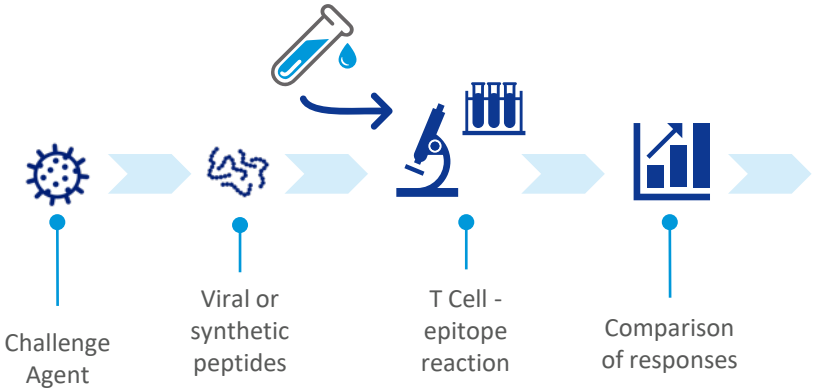
Step 1. T Cell Generation



No pathogen specific T Cells

Contains pathogen specific T Cells

Step 2. Vaccine Discovery



Challenge Agent

Viral or synthetic peptides

T Cell - epitope reaction

Comparison of responses

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

CanSinoBIO	moderna messenger therapeutics	INOVIO POWERING DNA MEDICINES	BIONTECH
Mkt Cap c. $4.5bn	Mkt Cap c. $68bn	Mkt Cap c$480m	Mkt Cap c. $41bn

AIM: POLB
OTCQB: POLBF

Stay in touch

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