POOLBEG PHARMA

Company Presentation

January 2023

AIM: POLB

OTCQB: POLBF

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A Leading Biopharma Company Specialising in Infectious Disease

Becoming a 'one-stop-shop' for pharma and biotech seeking programmes to in-licence

Spun out from

Deep roots in infectious disease & clinical trials

hVIVO *formerly* Open Orphan plc

Fully funded £18.9m cash (30 June 2022)

Smart, cost effective R&D approach

Targeting large addressable markets

Capital light & early out-licensing model

De-risking and unlocking the value of early programmes

Rapidly advancing exciting portfolio of programmes

Leveraging strong scientific rationale and smart clinical trial design to generate early human efficacy data

Multiple near term value inflection points

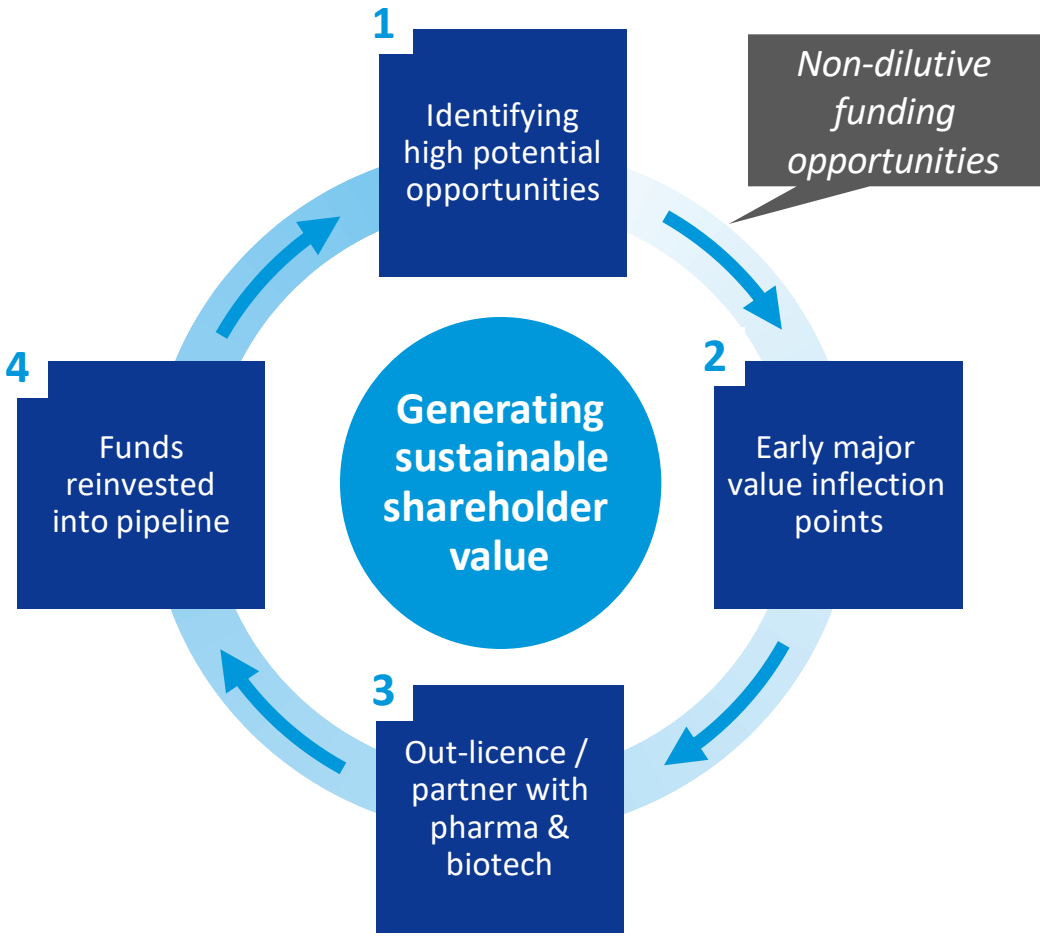
Global rights for all products

Open to territory specific partnering to maximise value

Active in-licensing & out-licensing model

A disciplined portfolio approach to mitigate risk, accelerate drug development and enhance investor returns

Four Steps To Generating Sustainable Shareholder Value



Portfolio approach – advancing multiple programmes in parallel

Multiple shots on goal – mitigating risk

Optimised asset selection:

- Clear market opportunity
- Attractive to partners
- Non-dilutive funding

Sustainable value creation

Experienced team in place to deliver upon the model

Progress being made across the portfolio

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. *RSV*

Pfizer licence Chinese rights LianBio
$20m upfront + $135m follow on, April 2022. *RSV*

Poolbeg's Exciting Pipeline of Assets

Pipeline – clinical development

Product Candidate	Pre Clinical	Phase I	Phase II	Phase III	Upcoming Catalysts
POLB 001 Severe influenza treatment					• LPS challenge trial: full data read-out expected Q2 23 • Out-licensing discussions initiated
POLB 001 CAR T cell companion therapy					• Clinical trial enabling activities 2023
POLB 002 Respiratory virus infections treatment & prophylactic					• Development plan completion
POLB 003 Melioidosis vaccine candidate					• Development plan completion

Product platforms

	Partner	Target Discovery	Product Validation	Animal Efficacy	IND Enabling	Upcoming Catalysts
AI Programme 1 RSV therapeutics	ONETHREE BIOTECH					• Lab-based validation 2023
AI Programme 2 Influenza drug targets	CytoReason					• Outputs expected Q2 '23
Oral Delivery Platform Licenced targeted delivery system	AnaBio™ Technologies	*Validated Technology & grant funded*		Vaccines		• Consortium workplan commencement • Fully funded by Irish gov. to IND ready status • Clinical trial commencement - H1 2023
		Validated Technologies		Metabolic Diseases		

Vaccine Discovery Platform

ViralPredict™

Exploring further in-licensing opportunities

POLB 001

Potential blockbuster immunomodulator

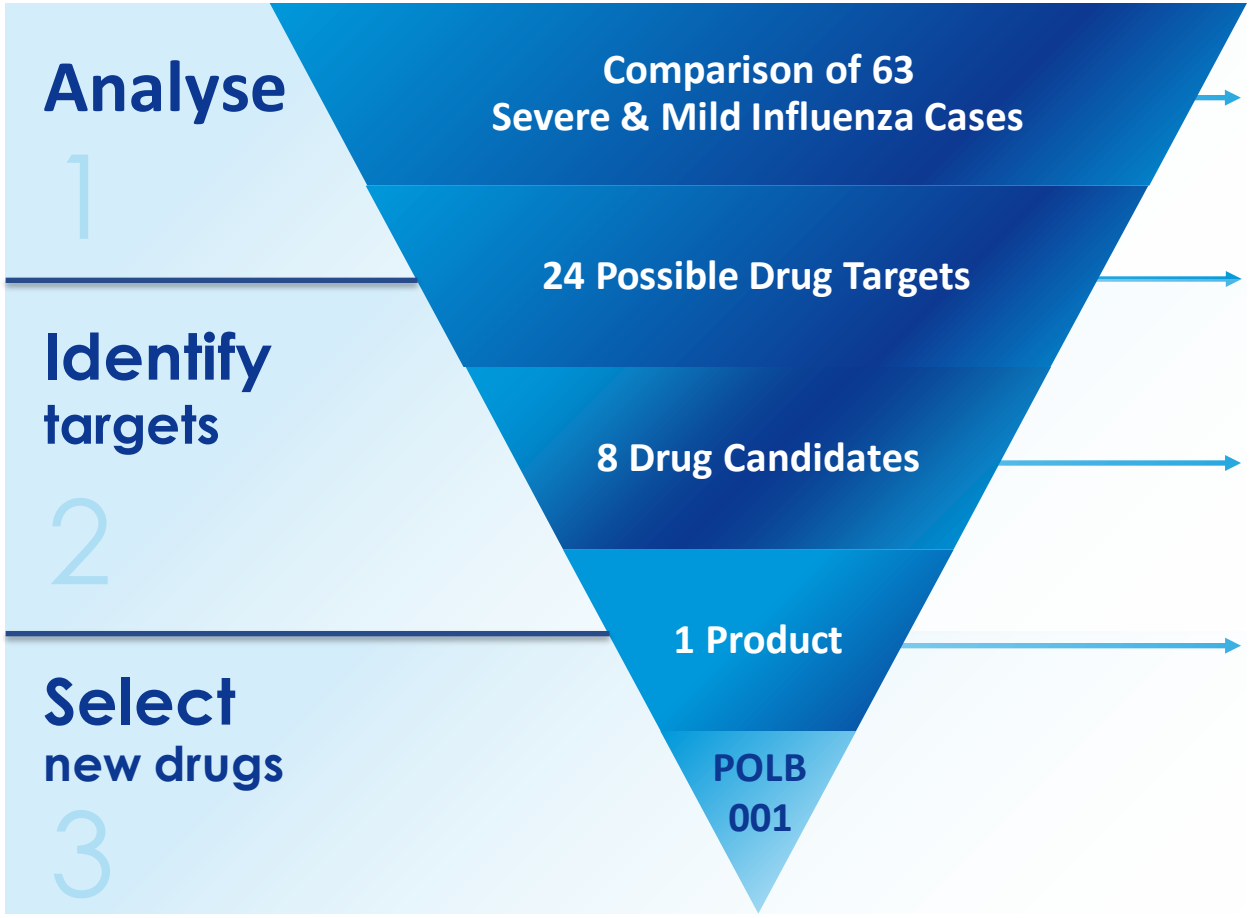
Significant opportunity across multiple disease areas

Severe influenza

Oncology

POLB 001 - Unique Data & Samples Identified

Road to identifying POLB 001 as the best p38 MAPK inhibitor



- Samples taken from patients with severe influenza were compared against human challenge trial 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

POLB 001 – Driving Meaningful Change for Patients by Dampening Cytokine Release Syndrome (CRS)

POLB 001

Potent anti-inflammatory immunomodulator
May have utility across *several diseases*

Hyper-inflammation: a source of toxicity in many patient groups
This includes *severe influenza* and *CAR T cell* patients*

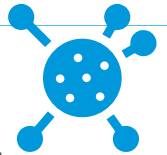
LPS challenge trial results
Potentially indicative of usefulness in other forms of CRS

Building increased value through multiple indications

Severe Influenza

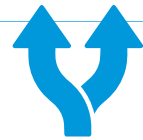
- LPS challenge trial completed Dec 22
- **Early data read-out** indicates a marked reduction in both systemic and localised inflammatory response & a clear dose-response relationship
- **Full data read-out expected Q2 2023** - discussions with potential partners initiated

Oncology



- Logical extension into oncology with the goal of addressing CRS in CAR T cell patients
- **IP filed Jan 2023** and progressing towards trial initiation in CAR T cell patients in 2024

Other Indications



- Evaluating other potential therapeutic indications where POLB 001 can be of benefit to fully unlock the value of the molecule

*Chimeric Antigen Receptor T cell

Potential to Block p38 MAPK Driven CRS

Benefitting severe flu patients, CAR T cell patients and beyond

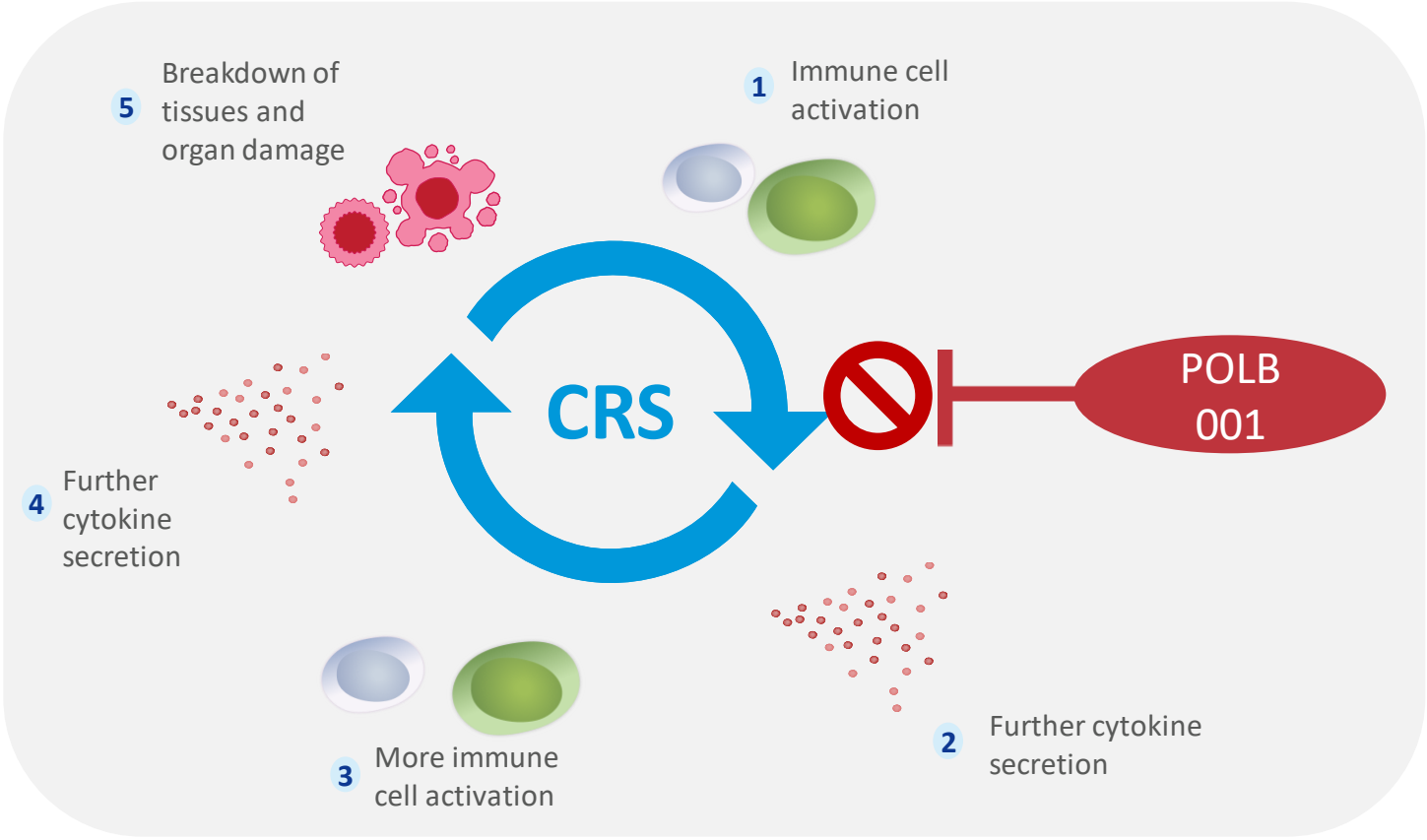
Severe influenza
Severe influenza infections causes hypercytokinaemia, also known as CRS

Other viral infections
Covid-19 and other respiratory viral infections can cause severe disease characterised by CRS

Cell therapy
New generation therapies that introduce engineered immune cells into the patient's body

Immunotherapy
A wide range of established therapies for oncology patients that encourage the patient's immune response to identify and destroy tumor cells

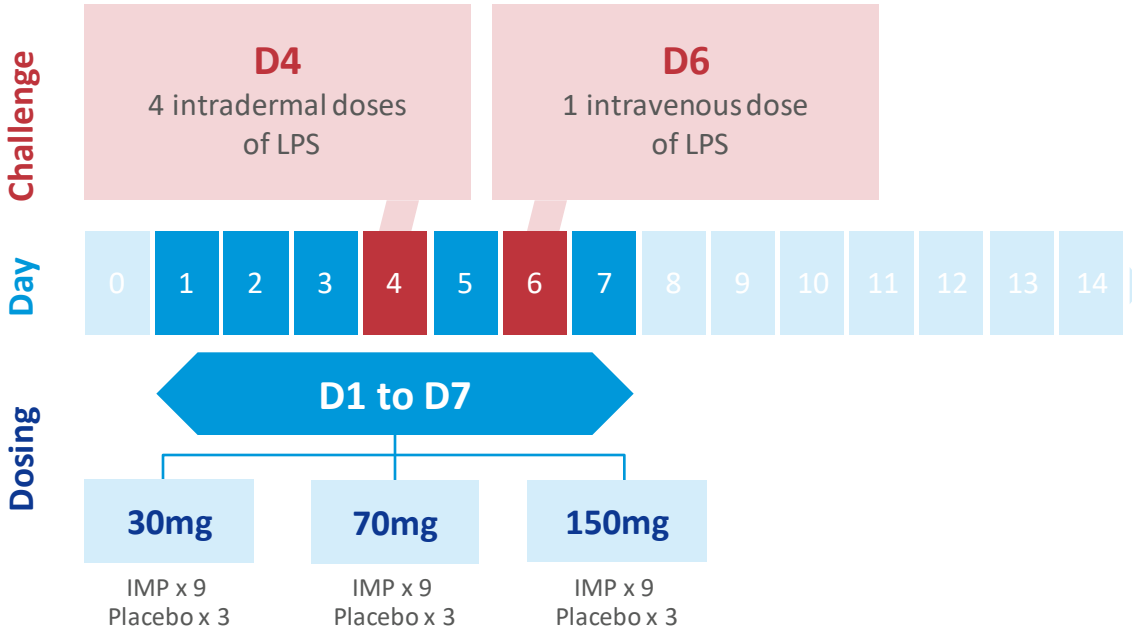
Immune over-activation



POLB 001 – p38 MAPK Inhibitor for Severe Influenza

Strain agnostic, shelf stable oral drug ideal for seasonal & pandemic stockpiling

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

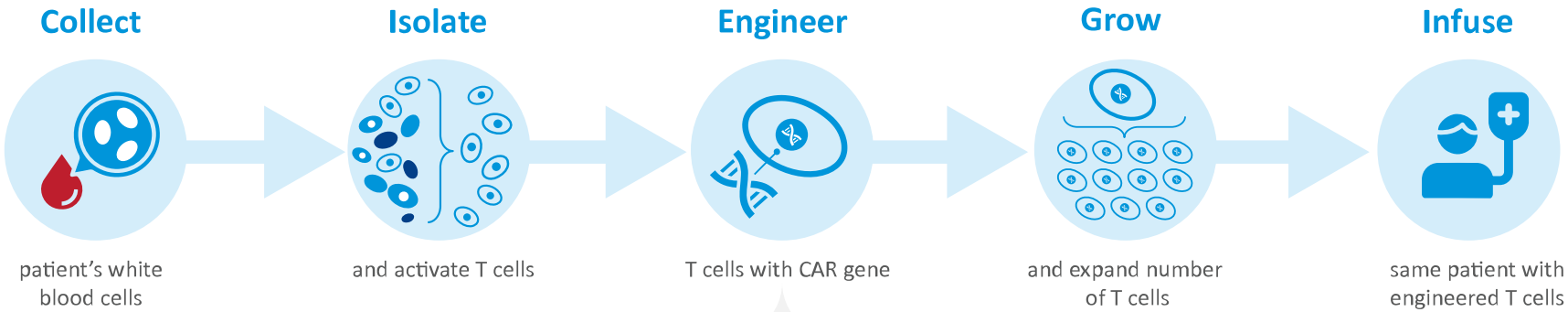


Positive initial data from LPS challenge trial

- Initial review of data from LPS challenge trial indicates that the trial has been successful
- Marked reduction in both local and systemic inflammatory response
- Clear dose response relationship
- Well tolerated across all doses and no serious adverse events reported
- Full data read-out expected Q2-23

CAR T Cell Therapy: Engineering Patient's Immune Cells to Treat Cancers

How does it work?



Derived from a patient's own blood or from a healthy donor
i.e. autologously or allogeneically

T-cells are engineered to be specific to an antigen on the surface of the tumour
but not expressed on healthy cell

Therapies are approved in advanced leukaemia and lymphoma

What is currently marketed?

Abecma (idecabtagene vicleucel) Suspension for IV infusion
Breyanzi
CARVYKTI (ciltacabtagene autoleucel) Suspension for IV infusion
KYMRIAH (tisagenlecleucel) Suspension for IV infusion
TECARTUS (brexucabtagene autoleucel) Suspension for IV infusion
YESCARTA (axicabtagene ciloleucel) Suspension for IV infusion

Beyond approved programmes, numerous additional CAR T cell therapies are in late-stage development

Source(s): Adapted from Kite Pharma – Cell Therapy Technology

CAR T Cell Associated Toxicities Such as CRS are a Challenge in the Clinic

Up to 95% of CAR T cell patients suffer treatment related side effects

Severe cases are life-threatening and may require intensive supportive care, including mechanical ventilation

Treatment is reactive at onset of signs

- Steroids and general organ support
- Anti-IL-6 receptor antibody (tocilizumab) - approved
- IL-1 receptor antagonist (anakinra) – used off label

Launch of POLB 001 Oncology Programme

IP expansion: targeting conditions where POLB 001 can treat hyperinflammatory diseases

Targeting CAR T cell patients who develop CRS

- ✓ Patent filed January 2023
- ✓ Collaborating with global experts
- ✓ Ongoing programme to enable clinical development
- Clinical trial initiation

Clear crossover between POLB 001's inflammation dampening effect in severe influenza and with CAR T cell patients experiencing CRS

Looking to Expand the Addressable Market for POLB 001 to Include Both Severe Influenza and CAR T Cell Patients

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Severe Influenza

3-5 Million

Severe influenza cases **globally**

500k+

Influenza-related respiratory deaths*

$2 Billion

Anti-viral market by 2025 (estimated)

No currently approved therapy

Oncology

18-19 Million

Annual cancer cases **globally**

9.5 Million+

Annual cancer deaths globally

$6 Billion

CAR T cell market by 2031 (estimated)

Existing CAR T cell therapies have seen associated toxicities in the clinic

Source(s): WHO website; The Lancet; Wayan C.W.S. Putri, David J. Muscatello, Melissa S. Stockwell, Anthony T. Newall, Economic burden of seasonal influenza in the United States, Vaccine, Volume 36, Issue 27, 2018, Pages 3960-3966, ISSN 0264-410X; *Estimates ranges from 290 – 650k. †3 – 5 million are estimated to be severe; CAR – T Cell Therapy Market Research - Allied Market Research 2021; Global Cancer Facts and Statistics - American Cancer Society

Artificial Intelligence Programmes

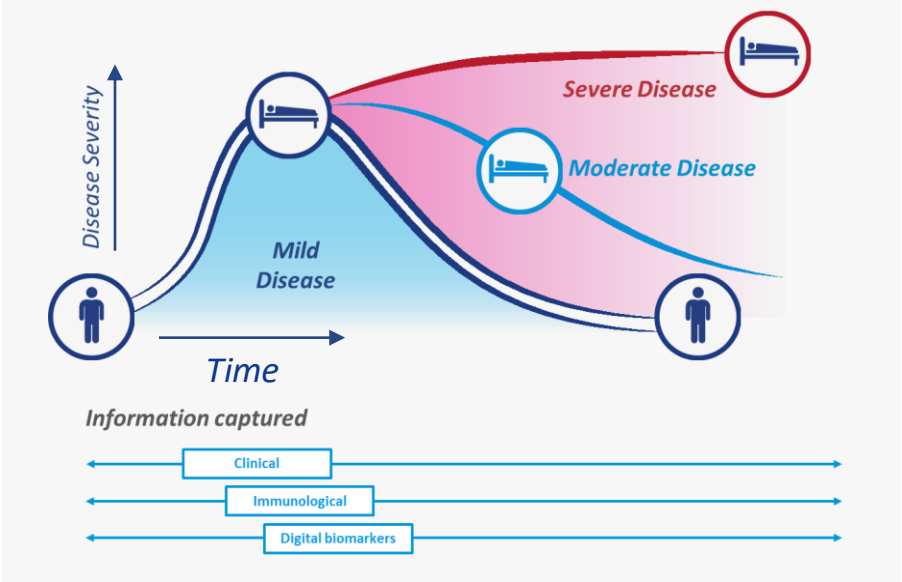
Unlocking the power of unique human challenge trial data

Influenza

RSV

Unlocking the Value in Human Challenge Trial Data

The first time AI is used to analyse RSV & influenza human challenge trial data



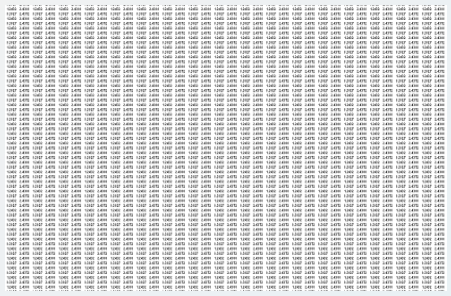
Cleaner data

- ✓ Known infection time
- ✓ Matched demographics
- ✓ Medical history

Greater precision

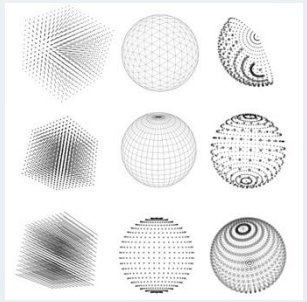
- ✓ Powered dataset
- ✓ Controlled GCP environment
- ✓ Exact viral burden
- ✓ Exact timing
- ✓ Commercial processing
- ✓ Deep sample analysis
- ✓ Controlled environment collection

Unstructured Data



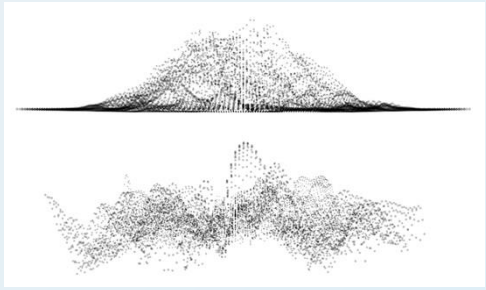
1. Raw or processed data points (e.g. challenge trial data)

Disease Model



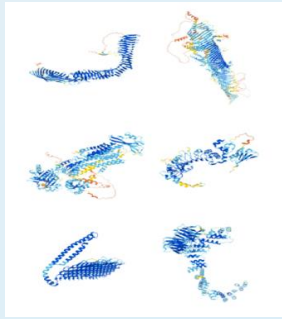
2. In silico reconstruction of disease

Signature Development



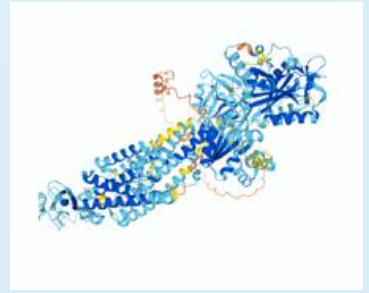
3. Identification of complex interplay
4. Bifurcation of biologically relevant insights

Target Identification



5. Identification of druggable nodes that can reverse or prevent disease signatures

Target Prioritisation



6. Prioritisation of insights based on data, KOLs and practical opportunities

Increasing Value

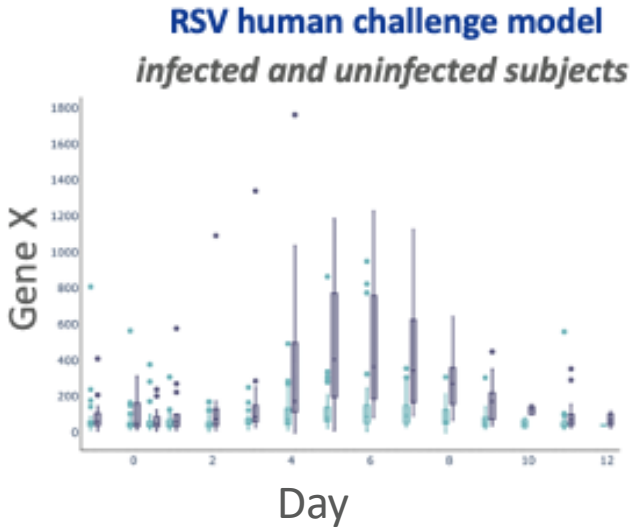
First Time RSV Drug Candidates Identified Using AI

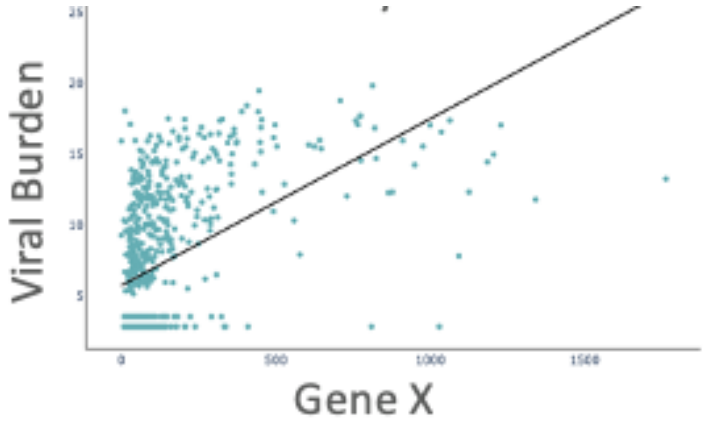
Respiratory syncytial virus (RSV)

ONETHREE BIOTECH

Prioritising drugs with existing Phase I safety data – reducing spend and risk

The goal is to identify a range of targets and drugs which will ameliorate the symptoms of RSV infection and which have not previously been investigated in the context of viral infection





AI-Identified Influenza Drug Targets Expected Q2 2023

Influenza

CytoReason

Contract Signed — Mar 2022

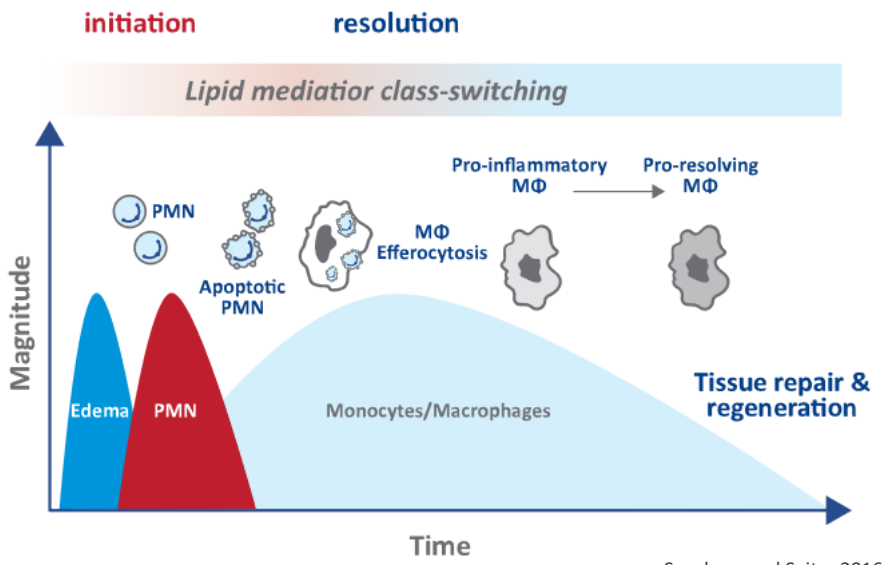
Model Build & Optimisation — Nov 2022

Outputs Expected — Q2 2023

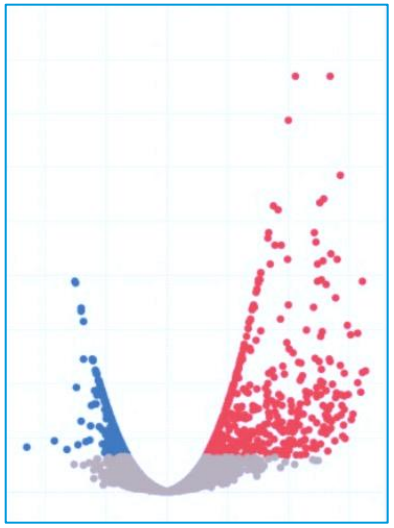
Identify products to in-licence

CytoReason work with several of the world's top pharma companies

Pfizer · Roche · MERCK · sanofi



Sansbury and Spite, 2016



Day 2 v Day 0 Infected

- Genes up regulated At baseline
- Genes up regulated D2 post infection

Oral Delivery Platform

Using innovative encapsulation technology

Significant opportunity across multiple disease areas

Vaccines

Metabolic syndrome related diseases

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Oral Vaccine Delivery Platform

Transformative oral vaccine platform funded by the Disruptive Technologies Innovation Fund (DTIF)

- Developing oral vaccine delivery platform that generates 'mucosal immunity'
  - Preventing pathogens from infecting the body
  - Prevent transmission of disease
- Large commercial opportunity
- Multiple disease indications

Disruptive Technologies Innovation Fund

Poolbeg-led consortium awarded €2.3m in non-dilutive funding to progress Oral Vaccine Platform

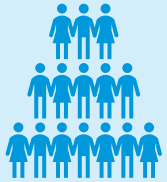
University College Dublin

AnaBio Technologies

Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

Oral vaccines can create mucosal immunity and reduce manufacturing challenges

Mass Vaccination
Pandemic has shown injections cannot give global protection



No Needles
Needle phobia has been shown to reduce vaccine uptake

Vaccine Hesitancy
People are more willing to take an oral product

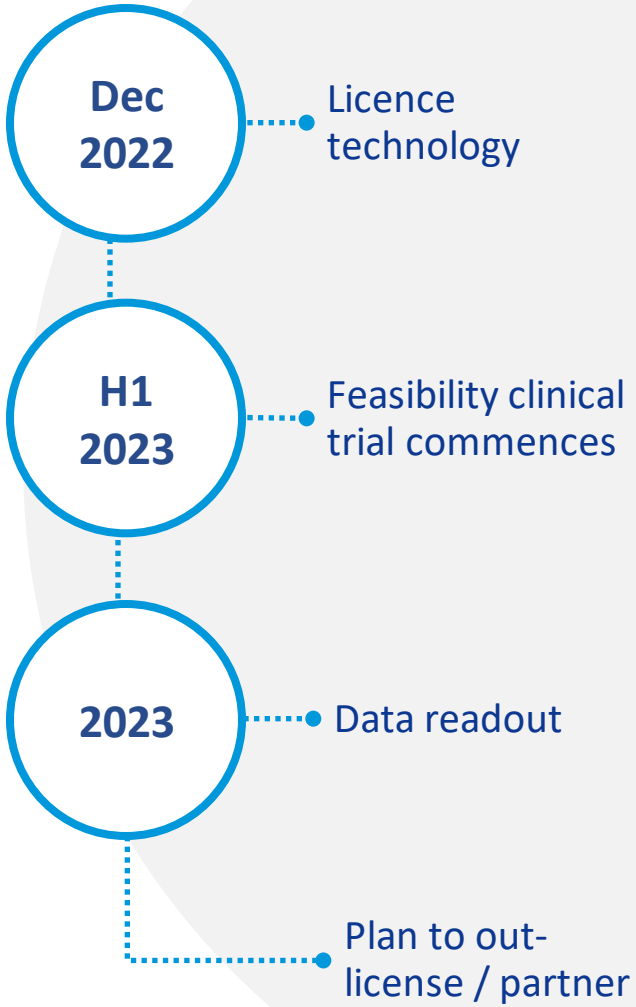
Easy Administration
Healthcare staff not needed

Cold Chain
Easy distribution and enhanced stability profile

Innovative Oral Delivery Technology for Metabolic Syndrome Related Diseases

Oral GLP-1 - clinical trial to commence H1 2023

Clinical trial to determine that the patented microencapsulation and nanoencapsulation technologies can safely deliver a Glucagon-like Peptide 1 receptor (GLP-1) agonist orally in humans



Oral delivery of GLP-1 solves many problems

Manufacturing & distribution advantages

- Often easier to produce
- Superior thermostability
- Reduced need for cold chain
- Longer shelf life
- Easier distribution

Mass access to treatment

- Easier to administer than an injection
- Reduced need for trained staff
- No needle phobia
- No needles, sharps or biohazard waste
- Lower cost of access

GLP-1 agonists, which are used to treat diabetes and obesity, represent an extremely large, fast-growing opportunity estimated to grow to c.$22bn per annum by 2025

Metabolic Diseases – A Fast Growing Market

Worldwide **obesity** has nearly tripled since 1975 & obesity treatment could quickly become a top-12 global therapy

>1BN

Obese people globally

$173BN

Cost to US Healthcare System annually

$54BN

Estimated global obesity sales in 2030

6X increase in sales in **diabetes** since 2000 with **GLP-1 representing ~15% of market** with continued growth expecting

>500M

Diabetics globally

$58.7BN

Global type 2 diabetes market 2025

Significant interest to develop therapeutics within the metabolic disease space

Eli Lilly enters deal with Nimbus for metabolic disease therapies

Deal for up to $496m through funding and milestone payments, Oct 2022

Eli Lilly and China-based Regor enter metabolic diseases deal

$50m upfront + $1.5bn follow-on, Dec 2021

Morgan Stanley Research

"the treatment of obesity is on the cusp of moving into mainstream primary care management"

Source: Morgan Stanley Research, December 2022; WHO, June 2021; IDF Diabetes Atlas, accessed December 2022; PharmaPoint: Type 2 Diabetes Market Analysis; Company press releases.

POLB 002

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

Novel approach to tackle respiratory virus infections

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POLB 002 – A Global Need for Respiratory Virus Infection Products

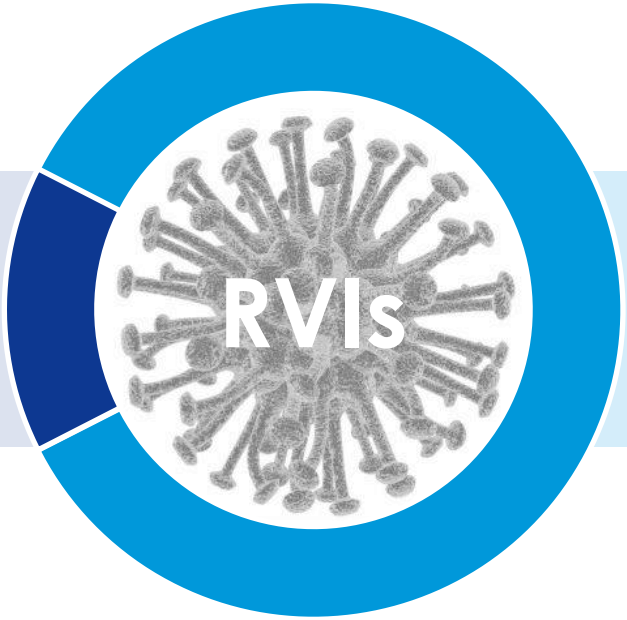
Most respiratory virus infections cannot be treated

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

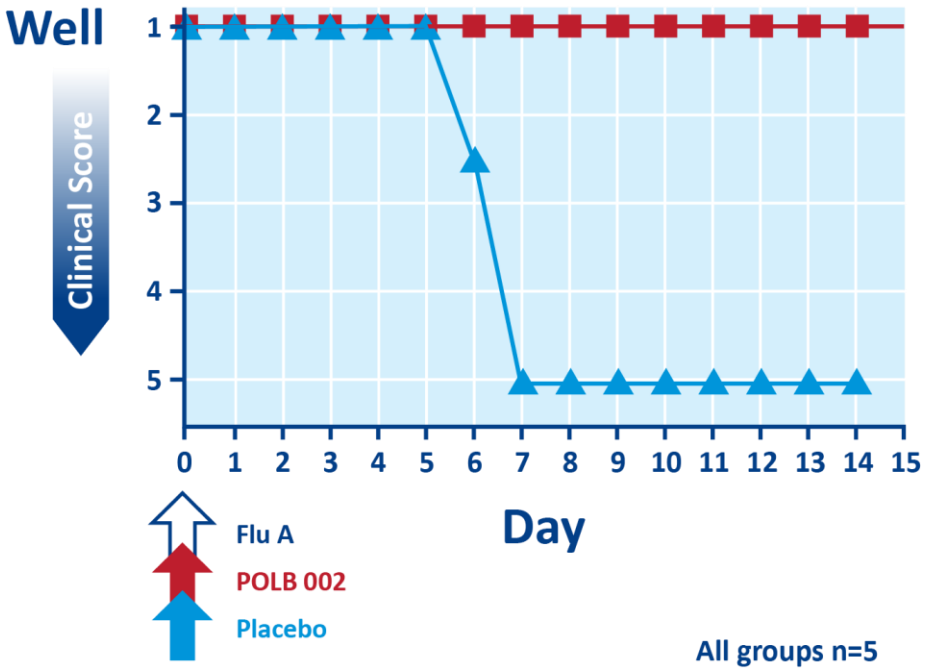
First-in-class, broad spectrum, RNA-based

- Derived from 20 years research by world class researchers
- 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

Respiratory Virus Infections

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

In vivo influenza A challenge



Source(s): 1. WHO, The top 10 causes of death. Newsroom Fact Sheets, 2020. 2. Internal, data on file.

POLB 003

Vaccine candidate for melioidosis

Late preclinical stage

POLB 003 – Melioidosis Vaccine Candidate

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Background to melioidosis

- *Burkholderia pseudomallei* causes severe disease in humans & animals
- Infection routes: inhalation, percutaneous inoculation (through an open wound), & ingestion (food or water)
- Treatment: lengthy antibiotic treatment for up to 6 months
- Antibiotic resistant
- Significant underreporting of cases

165,000
estimated cases per annum

54%
of cases are fatal

0
vaccines available

"Predicted increases in temperature, changes in global precipitation patterns and an increased incidence of extreme weather events are expected to change melioidosis epidemiology."

Adam J Merritt, et al, 2017

CDC designated Tier 1 Select Agent Biothreat

- Recent outbreak highlights the Biothreat of Melioidosis – creating stock piling potential

Forbes

HEALTHCARE

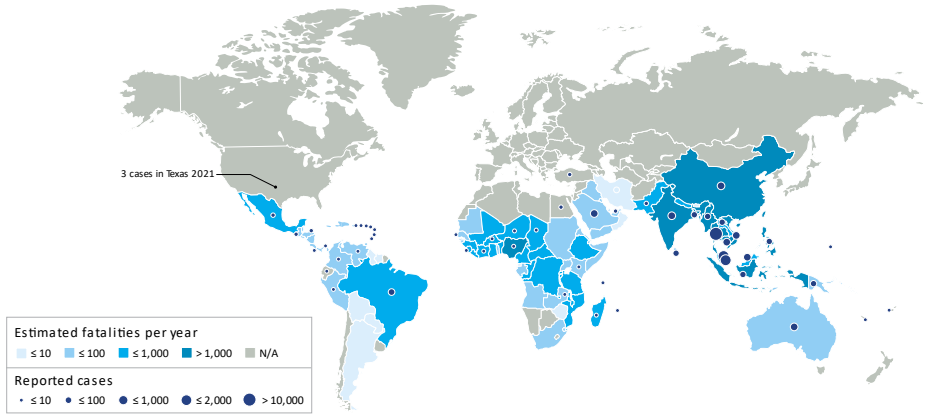
CDC Sleuths Find Source Of Deadly Melioidosis Outbreak Is A Room Spray Sold At Walmart Oct, 2021

The Standard 英文虎報

Hong Kong

Six dead from rare bacterial infection

Top News | Jane Cheung 13 Oct 2022



Source: 1. Gassiep I, Armstrong M, Norton R. Human Melioidosis. *Clin Microbiol Rev*. 2020;33(2):e00006-19. Published 2020 Mar 11. doi:10.1128/CMR.00006-19; 2.Wiersinga, W., Virk, H., Torres, A. *et al.* Melioidosis. *Nat Rev Dis Primers* 4, 17107 (2018). https://doi.org/10.1038/nrdp.2017.107.

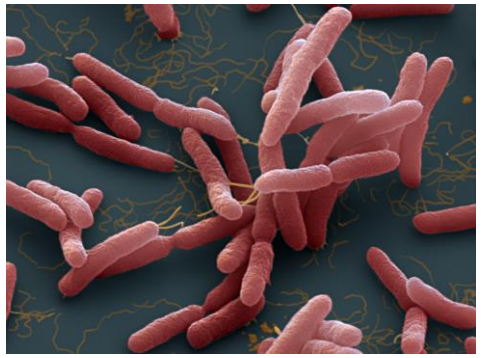
POLB 003 – Melioidosis Vaccine Candidate

POOLBEG PHARMA

Late pre-clinical stage

Efficacy data

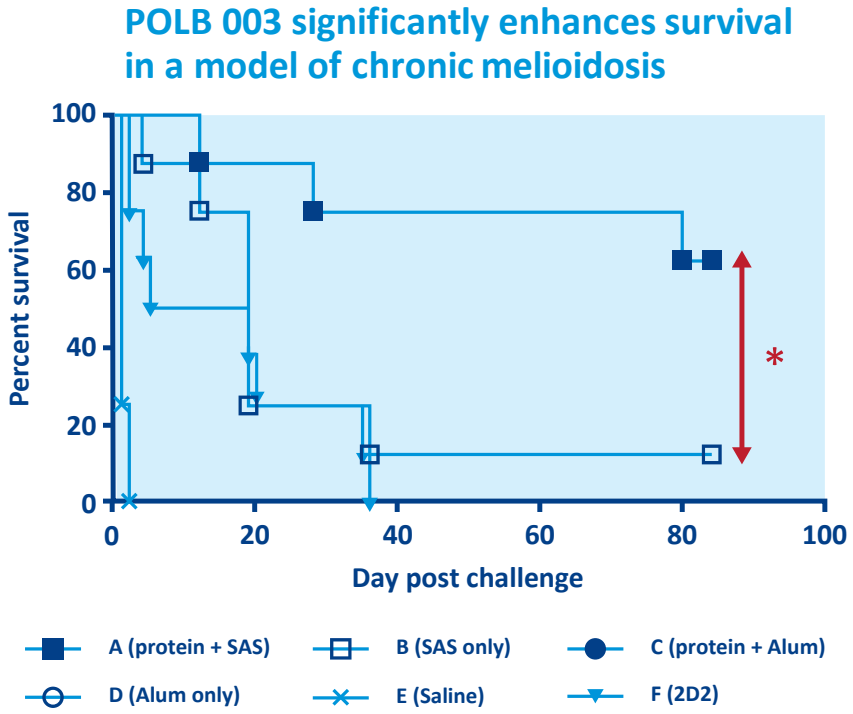
- 75% survival rate of immunized mice over 81 days
- Subsequent characterisation of immune responses confirmed T-cell (CD25 and CD44 activation) and B-Cell responses required for an effective vaccine
- As diabetes is a substantial comorbidity, a standalone insulin resistance mouse model was created that demonstrated activation markers and cytokine production associated with immunoreactivity, giving confidence of translation to this vital patient sub-population



Burkholderia pseudomallei

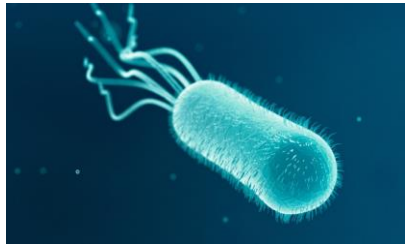
Safety data

- No safety signals in GLP toxicology study



Additional Vaccine Candidates from UCD

Option agreement for 5 additional vaccine antigen candidates

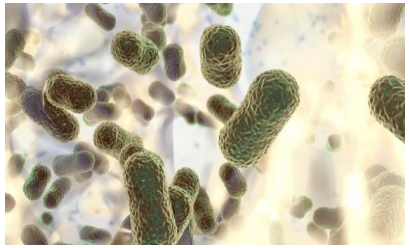


O157 E.coli/STEC/ VTEC

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

Pseudomonas aeruginosa

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

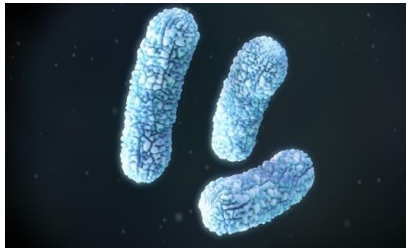


Acinetobacter baumannii

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

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

Strong Investment Case

Several compelling reasons supporting Poolbeg's investment case

Near Term Value Inflection Points

1

- POLB 001 – full data read-out expected Q2 23
- RSV AI programme – lab-based validation stage
- Influenza AI programme – outputs expected in Q2 2023
- DTIF funded Oral Vaccine Platform – Consortium workplan commencement 2023
- Commencement of GLP-1 feasibility Clinical Trial – H1 2023
- POLB 001 expansion to oncology – trial enabling activities in 2023

Experienced Team

2

- Exceptional track record having previously created c. $2 billion in shareholder value
  - Evident in recent $1.48bn Amryt Pharma acquisition
- Strong focus on Business Development as partnering discussions continue
- Addition of experienced SAB member

Smart, Capital Effective Model

3

- Disciplined capital allocation – cost effective R&D approach
- Well capitalised with cash balance of £18.9m (30 June 2022)
- Accessing non-dilutive funding opportunities
  - *First award*: €2.3m for Oral Vaccine Platform

Targeting Large Addressable Markets

4

- Core focus on the booming infectious disease market with expected value >$250bn by 2025
- Companion therapy in the CAR T cell market which is expected to grow to $6bn by 2031
- Global obesity sales expected to hit $30bn by 2030. Global type 2 diabetes market to reach $58.7bn by 2025

Poolbeg is well positioned to create sustainable shareholder value into the future

Source: Morgan Stanley Research, December 2022; Cowen: Obesity Market 2022; IDF Diabetes Atlas, accessed December 2022; PharmaPoint: Type 2 Diabetes Market Analysis; Company press releases.

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Appendices

AIM: POLB
OTCQB: POLBF

Experienced Leadership Team

Cathal Friel
Chairman

- Co-founder & Chairman of hVIVO plc
- Co-founder & shareholder in Amryt Pharma plc; leading Nasdaq orphan drug company – sold for $1.48bn
- 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 hVIVO plc (formerly Open Orphan plc) - 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 hVIVO plc & Poolbeg Pharma plc
- Managed multiple funding rounds of in excess of £47m
- Managed & maximised hVIVO'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

POOLBEG PHARMA

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

Sultanah Rajbally

Global Programme Director

- Bachelor of Science degree from Birkbeck University, London.
- 14+ years in pharmaceutical & biotech industry
- Previously Director of Clinical Development at Crescendo Biologics Limited & as Associate Director of Clinical Development at AstraZeneca.

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

David English

VP of Business Development

- > 16 years of diverse scientific & business experience across the pharma, biotech & medical device industries.
- Prior to joining he worked at the global biopharmaceutical Alkermes.
- Senior positions at Johnson & Johnson and Creganna Medical,

Scientific Advisory Board Members

Elaine Sullivan, PhD

- CEO Dargle Therapeutics & Exec Chair Keltic Pharma
- 25 years in biopharma including VP Global External R&D at Eli Lilly
- Raised $100m for Carrick Therapeutics as Founder
- NED: hVIVO, IP Group, Active Biotech Supervisory Board Evotec

Prof Luke O' Neill

- World-renowned immunologist
- Chair of Biochemistry at School of Biochemistry & Immunology at Trinity College Dublin
- Fellow, Royal Society & Royal Irish Academy Gold Medal for Life Science

Daniel F.Hoft, MD, PhD

- Director of Infectious Diseases Division, Allergy & Immunology at St Louis University (SLU) School of Medicine
- Principal Investigator of SLU's Vaccine & Treatment Evaluation Unit
- 32 years in immunology & ID

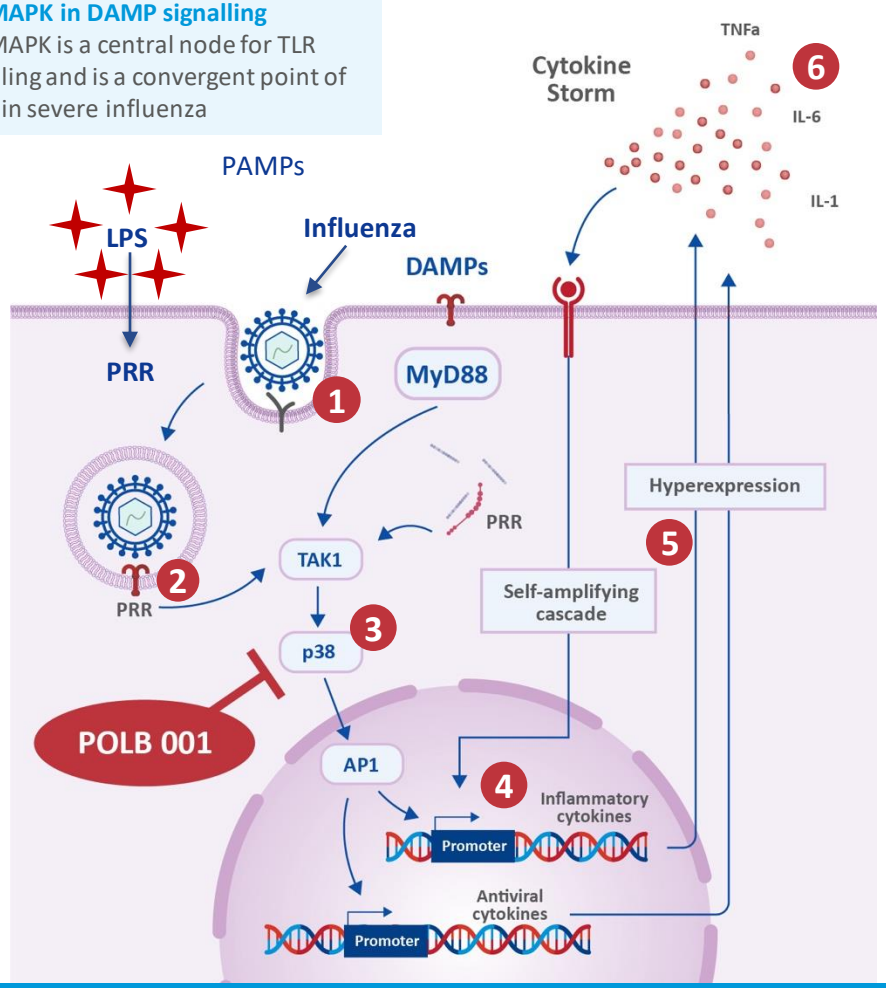
Prof Brendan Buckley

- Former Chief Medical Officer at ICON plc
- 40 years' experience in clinical practice as a Consultant Physician in endocrinology, diabetes and in academic clinical pharmacology
- Published over 150 scientific papers,

POLB 001 – a Broad, Pan-Viral Mechanism of Action

Targeting post anti-viral treatment window (48 hrs+)

p38 MAPK in DAMP signalling
p38 MAPK is a central node for TLR signalling and is a convergent point of focus in severe influenza



1. Infectious pathogen infects cells of the respiratory tract
2. Pattern recognition receptors are activated by endosomal and cytoplasmic viral antigens
3. A signalling cascade involving p38 MAPK 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

LPS signalling

Similar to severe influenza, proinflammatory expression of TNFα, IL-1β, IL-6 and IL-8 are reliant on p38 MAPK activity following LPS stimulation

In vivo clinical pharmacokinetics

Prior to patient testing Poolbeg Pharma are confirming the potential of POLB 001 to exert a clinically meaningful dampening of severe inflammation by using an LPS challenge trial

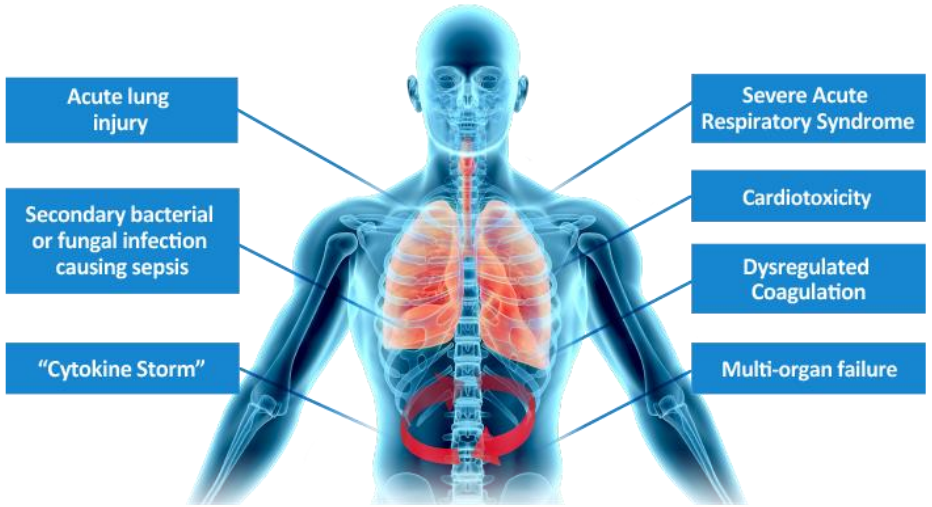
POLB-001 LPS challenge trial full data read-out expected Q2 2023

PAMP: Pathogen-Associate Molecular Pattern; **DAMP**: Damage-Associated Molecular Pattern

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.

POLB 001 – Successful Phase I Study Already Completed

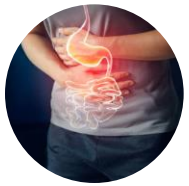
Safety & tolerability demonstrated – rapid progression to challenge study

Phase I 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

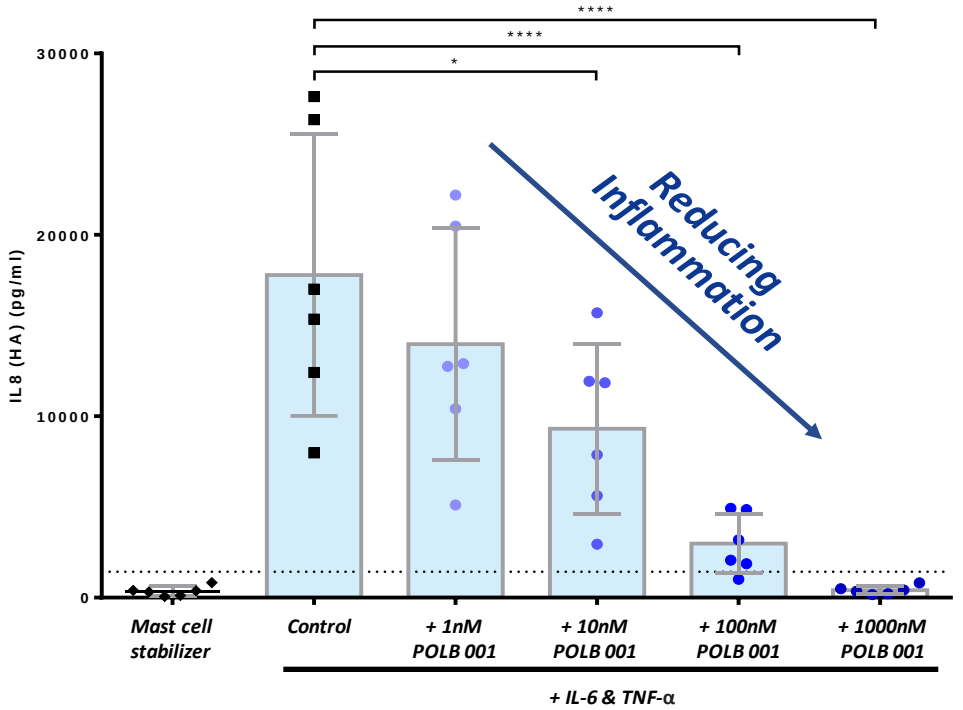
Safe and well-tolerated
After administration of single doses up to 600 mg and repeated doses up to 150 mg, there were neither serious nor limiting adverse events to POLB 001

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)

Dose dependent reduction in inflammation



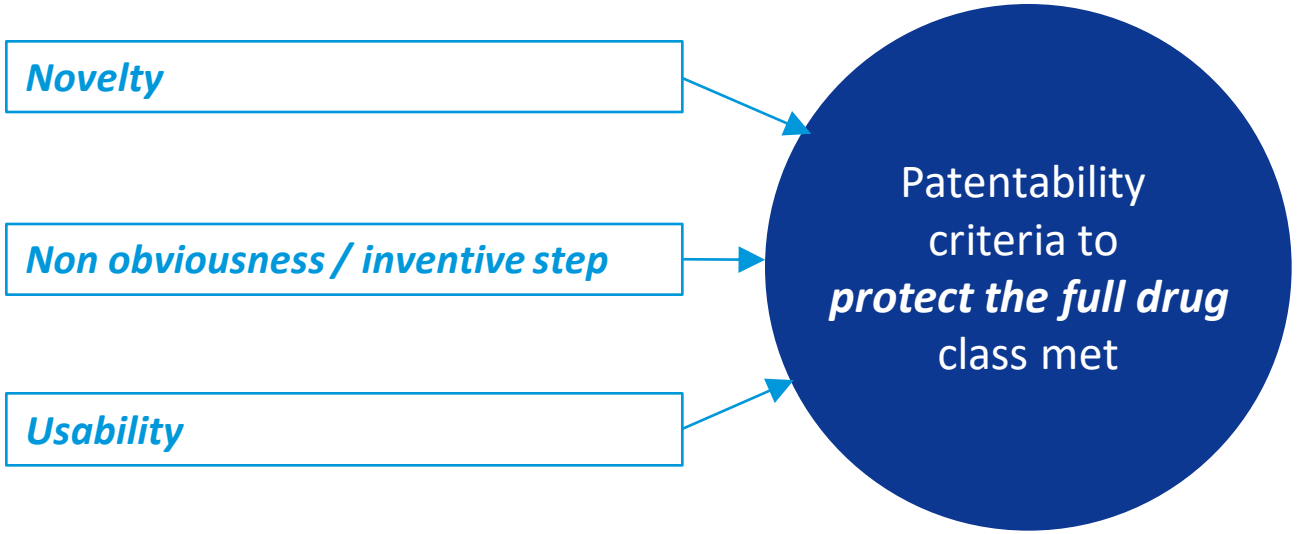
To simulate hyperinflammatory conditions, immune cells were treated with IL-6 and TNF-α, and IL-8 was used as a marker to measure resulting inflammation. The addition of POLB 001 reversed the inflammatory response in a dose dependent manner.

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

Patent Protection Strategy

Drug class protection

- There are p38 MAPK inhibitors that are in development, have been shelved or are available for out licensing
- No p38 MAPK inhibitors have been developed for use in CAR T cell related toxicities, although preventing CRS has been an area of interest



Patent filed January 2023

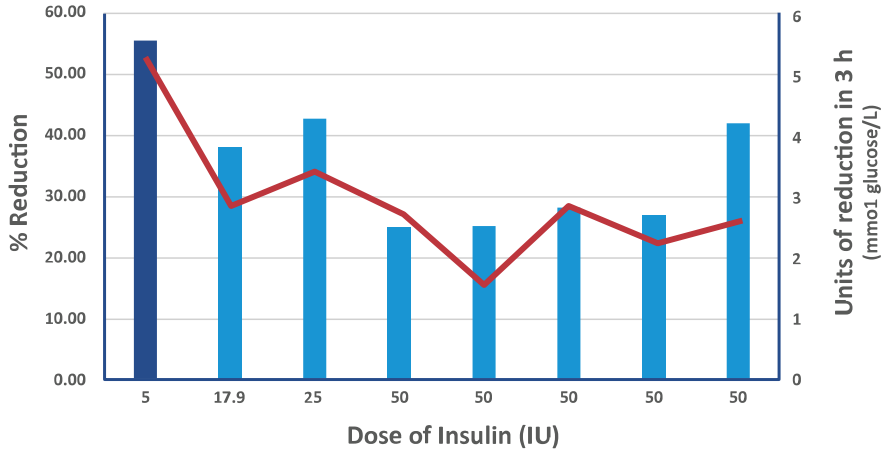
- Patent is unrelated to previous filings related to POLB 001 in influenza and claims a 2023 priority date
- Patent covers a method of use of all p38 inhibitors during CAR T cell treatment
- While investigating the role of CRS in Influenza, Poolbeg discovered data specific to the immune response in CAR T cell patients which suggests POLB 001 is an potential treatment option for these patients
- The company believes further IP expansion is possible to further increase the addressable market

Proof Of Concept: Insulin & GLP-1 Agonist Liraglutide

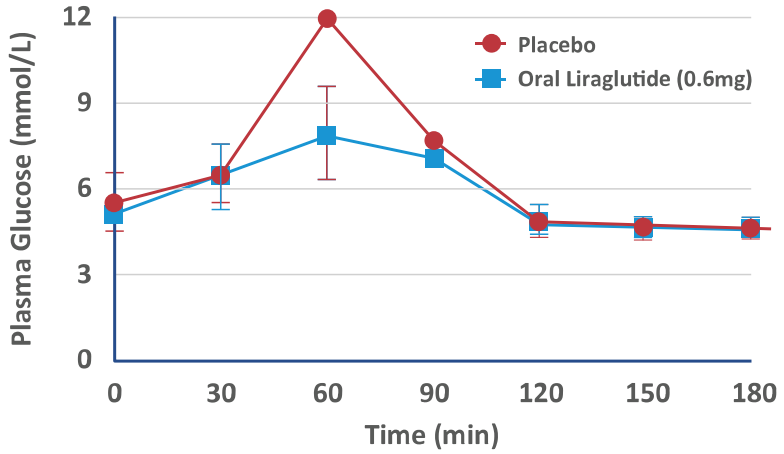
Proven delivery of intact peptide to the gut

- In small scale clinical trials oral dosage of both **insulin** and **liraglutide** were shown to reduce blood glucose levels compared to placebos.
- Insulin trials with Type 1 diabetics using different oral doses from 18 IU to 50 IU, showed an average reduction of 25 – 30 % of the glucose levels 3-4 hours after ingestion of encapsulated insulin.
- Similar results observed with Liraglutide, which used to treat type 2 diabetes, obesity, and chronic weight management.

Orally ingested encapsulated Insulin and Liraglutide show similar effects to injected equivalents



Effects of oral dosage of micro-encapsulated Insulin on blood glucose levels



Effects of oral dosage of micro-encapsulated Liraglutide on blood glucose levels

Oral Peptides: Protecting the Payload

Processing

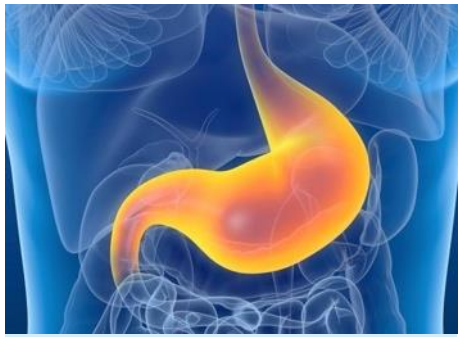
Processes suitable for use with heat labile and sensitive APIs

Storage

Solid product is shelf stable for months to years

Consumption

Product can be ingested as a solid, as part of a food product or in solution



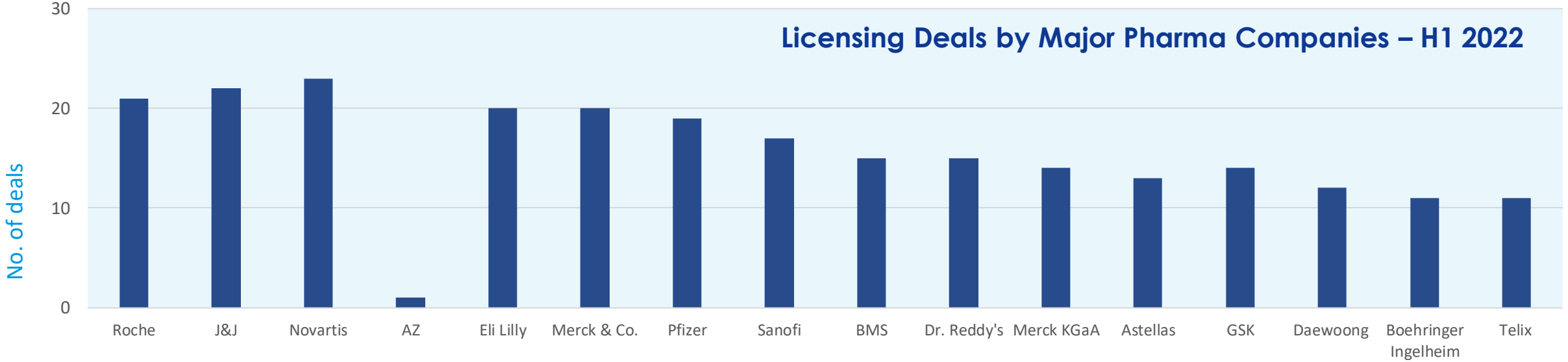
Stomach

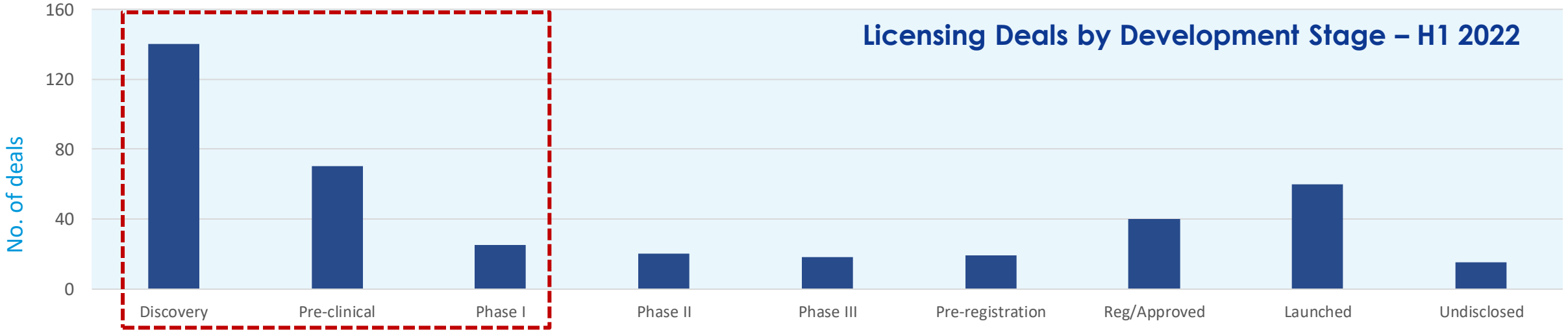
API is 100% protected from harsh stomach environment

Target

Uptake can occur via passive uptake from the gut lumen or be assisted by permeation enhancers and mucoadhesives

$68 Billion Worth of Licensing Transactions Took Place in H1 2022

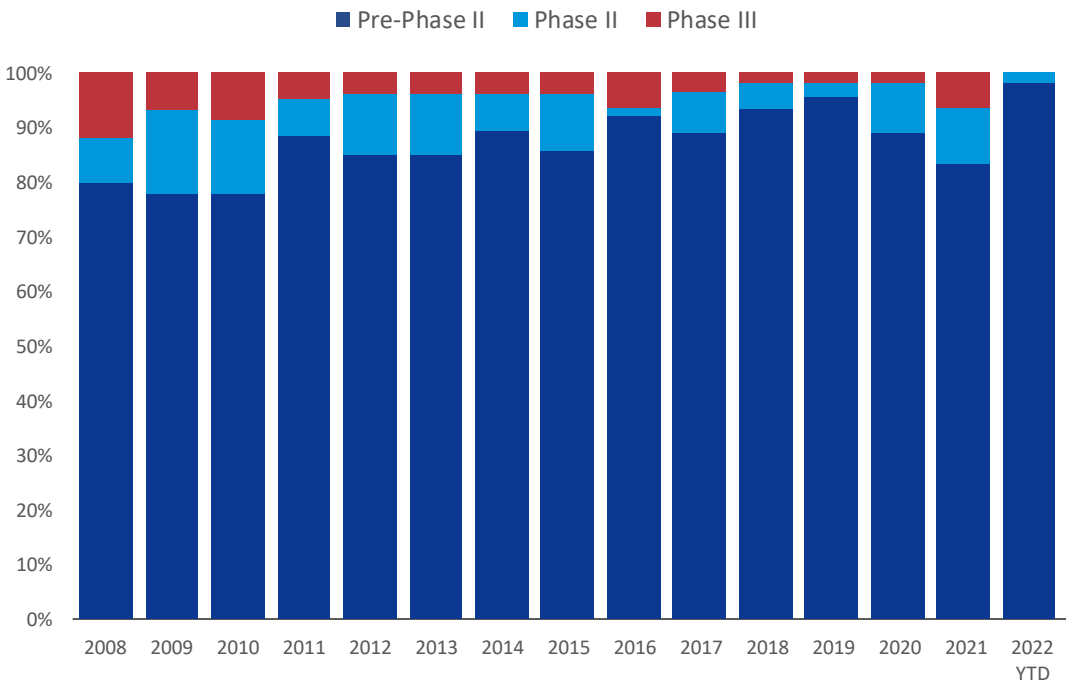




Source: IQVIA Pharma deals H1 2022.

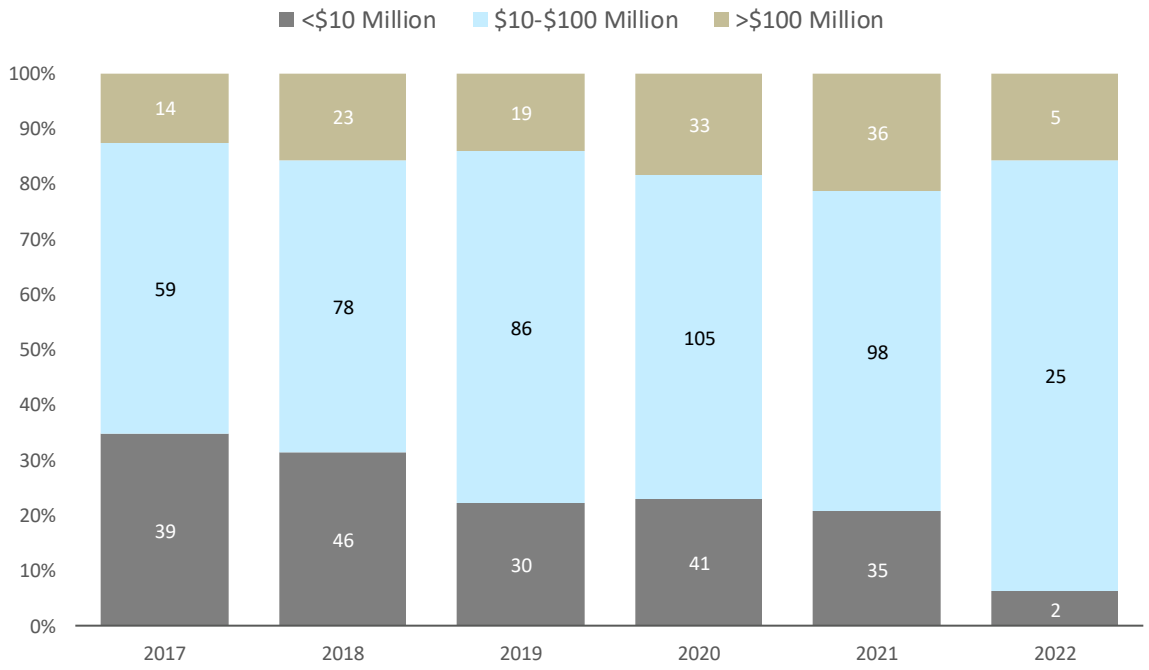
Big Pharma is In-Licensing Earlier and Out-Licensors are Receiving Larger Upfronts in Deals

In-Licensing by Large Cap Biopharma ($50B): Share of R&D Partnerships by Stage



Over 90% of Q1 2022 in-licensing partnerships were pre Phase II

Share of Deals by Range of Upfront Cash & Equity



Many R&D licensing partnerships bring in strong upfront payments

A significant focus on early stage programs aligns with the unique operating model of Poolbeg Pharma

Source: JP Morgan – Biopharma Therapeutics and Licensing Deals and Venture, April 2022.

Cultivating Collaboration Through In-Licensing

Partnering to make meaningful change within life-threating infectious diseases

Complimenting partners innovation with our internal expertise

Search
Defined areas of interest

Engage
Partners for initial conversations

Agree
On the optimal way to work together

Deliver
A lasting partnership

Programme stage of interest

Near-term (6-12 months) clinic ready

Therapeutic focus (Modality agnostic)

Immunomodulators

Antivirals

Antifungals

Vaccines

Actively exploring in-licensing opportunities in rare and emerging infectious disease

Out-Licensing to Pharma Following Early Human Efficacy Data Aids the Commercialisation of Novel Medicines

Partnering to make meaningful change within life-threating infectious diseases

Accelerating partners infectious disease R&D development

Rapidly advancing exciting portfolio of programmes

De-risking and unlocking the value of early infectious disease programmes

U.S. & Europe

Primarily focused on U.S and European markets for a strategic deal

Engaging early with select partners on **POLB 001** ahead of initial LPS challenge trial data

Rest of World

Initiating preliminary regional partnering discussions for POLB 001, POLB 002 and POLB 003

Open to partnering China rights and other Asian territories

Assessing interest in collaboration opportunities based on AI-enabled novel targets identified in RSV and ongoing influenza efforts

ViralPredict™ Biomarker Platform for Predicting Severe Disease

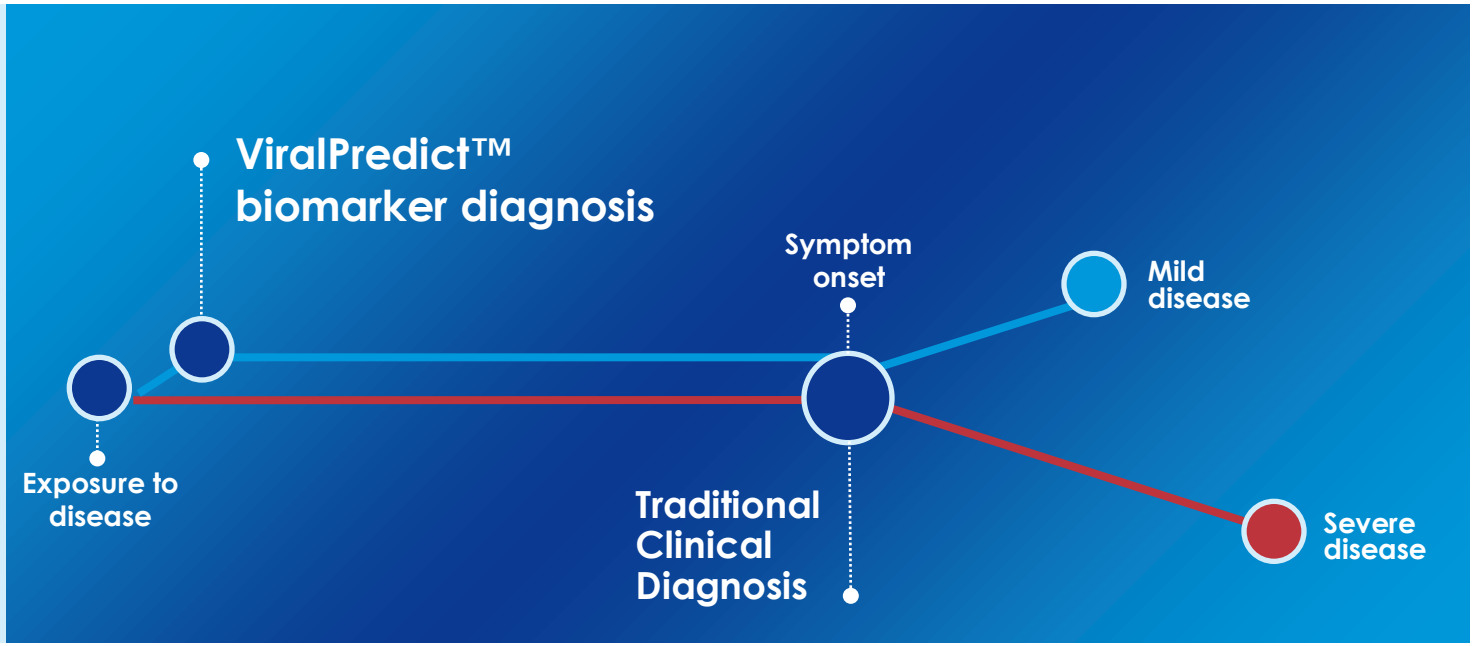
Potential to transform the way infectious diseases are treated, opportunity to licence this tool to Big Pharma

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

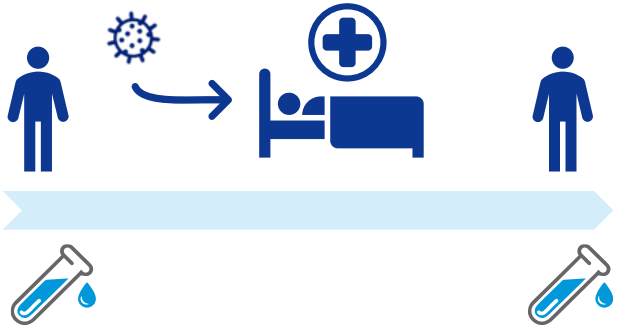
ViralPredict™ Biomarker Diagnostics vs Traditional Diagnosis of Disease



Unique Vaccine Discovery Platform

Harnessing the human challenge model to discover new vaccines

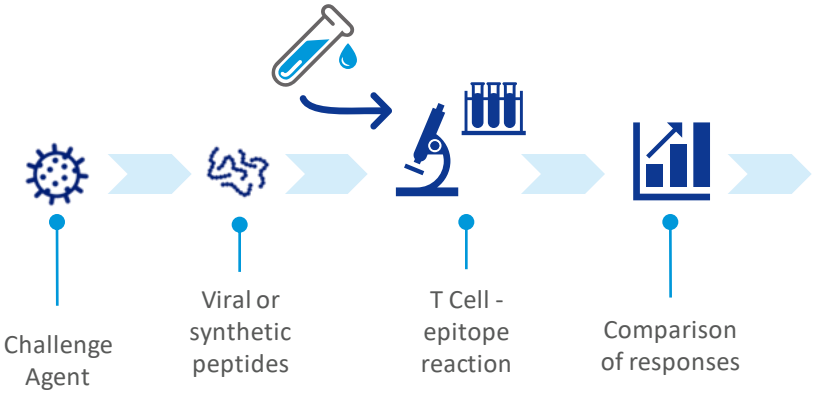
Step 1. T Cell Generation



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. $5.5bn	Mkt Cap c. $67bn	Mkt Cap c$474m	Mkt Cap c. $39bn

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