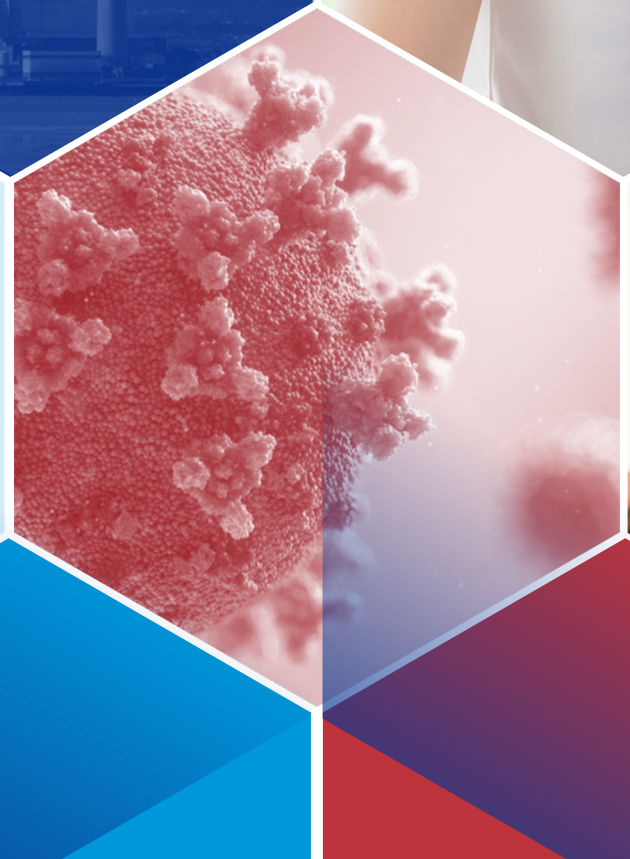

POOLBEG PHARMA

A Portfolio of Innovative Treatments for Diseases with Unmet Medical Need

October 2023

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Developing Innovative Medicines to Address Unmet Needs

Pipeline targeting large addressable markets

Using AI to Identify Novel drug targets with unique human challenge trial data

- AI-led discovery programmes with OneThree Biotech targeting RSV and CytoReason targeting Influenza

Team with Exceptional Track Record

- Proven track record of value creation - c. $2 billion in shareholder value
- e.g. $1.48bn Amryt Pharma acquisition 2023
- Strong focus on BD as partnering discussions continue

Unique Business Model

- Disciplined portfolio approach to mitigate risk, accelerate drug development, and enhance investor returns
- Committed to generating early revenue through partnerships

Strong Financial Position

- Capital efficient operating model
- Cash balance of £14.1m (30 June 2023)
- Proven ability to secure non-dilutive grant funding

Significant Progress Made in 2023

Well positioned for future growth

- **Positive results** from LPS human challenge trial for POLB 001
- **Strategic expansion** of POLB 001 into Oncology
- Identified **multiple novel drug targets** for influenza as part of AI-led programme
- Lab based validation of **RSV drugs identified** using AI ongoing
- Oral Vaccine Programme **encapsulation validation** ongoing
- Oral GLP-1 agonist proof-of-technology **clinical trial design refined**
- **Strategic collaboration** with Nasdaq listed biopharma on oral delivery for a metabolic disease

Exciting Portfolio of Products & Partnerships

Product Pipeline

Product Candidate	Pre-Clinical	Phase I	Phase II	Phase III	Key Catalysts
POLB 001 Severe Influenza					Positive LPS Challenge Trial data Phase 2 & partnering ready
POLB 001 Oncology					Phase 2 ready Discussions with prospective partners ongoing
POLB 002 Respiratory Virus Infections Treatment & Prophylactic					Development plan completion
POLB 003 Melioidosis Vaccine Candidate					Development plan completion

Global rights for all pipeline products

Partnerships

	Partner	Target Discovery	Product Validation	Animal Efficacy	IND Enabling	Key Catalysts
AI Programme 1 RSV therapeutics	OneThree Biotech					Lab-based validation 2023
AI Programme 2 Influenza drug targets	CytoReason					Outputs received Q2 2023; Validation in 2024
Oral Delivery of GLP-1 agonist Obesity & diabetes treatment	AnaBio™ Technologies	*Validated technology*				Proof of technology clinical trial commencement H1 2024
Oral Vaccine Platform Licenced targeted delivery system	AnaBio™ Technologies	*Awarded DTIF[1] grant funding*				Encapsulation validation expected H2 2023

[1] Irish Government's Disruptive Technologies Innovation Fund (DTIF)

POLB 001

Potential blockbuster immunomodulator

Opportunity across multiple disease areas

Severe influenza

Oncology

POLB 001- Clinical Stage Potential Blockbuster Immunomodulator

Benefitting severe flu patients, oncology patients and beyond

- A clinical stage, **Phase II ready**, oral small molecule immunomodulator that blocks p38 MAPK to inhibit inflammation in humans
- **Phase I** study – safe and well tolerated, predictable and durable exposure, demonstrated inhibition in LPS ex-vivo challenge
- Subsequent **Phase Ib** LPS challenge trial successfully completed with positive data generated
- Shelf-stable drug - ideal for stockpiling
- Potential utility across several acute, inflammatory diseases including **Cytokine Release Syndrome** (CRS) associated with severe influenza & oncology treatments
  - Patent protection until 2038 for severe influenza
  - Oncology patent applications filed in 2023

Large Addressable Markets

- Influenza contributes to an estimated total economic burden of $11B+ in the U.S. alone
- 3 - 5 million severe influenza cases globally with no suitable drug on the market
- Large unmet medical need for managing CRS induced by oncology immunotherapies

Mechanism of Action of POLB 001

Potential to block the progression of life-threatening Cytokine Release Syndrome (CRS)

Drivers of CRS

- CRS is a severe inflammatory response triggered by an overproduction of immune cells (over-activation), also known as hypercytokinaemia or 'cytokine storm', often seen as a side effect of viral infections and some therapies

Cytokine Release Syndrome Cycle

- Symptoms range from mild flu-like symptoms to severe, life-threatening reactions
- p38 MAPK is a protein that plays a key role in the production of inflammatory cytokines, and its overactivation can contribute to CRS

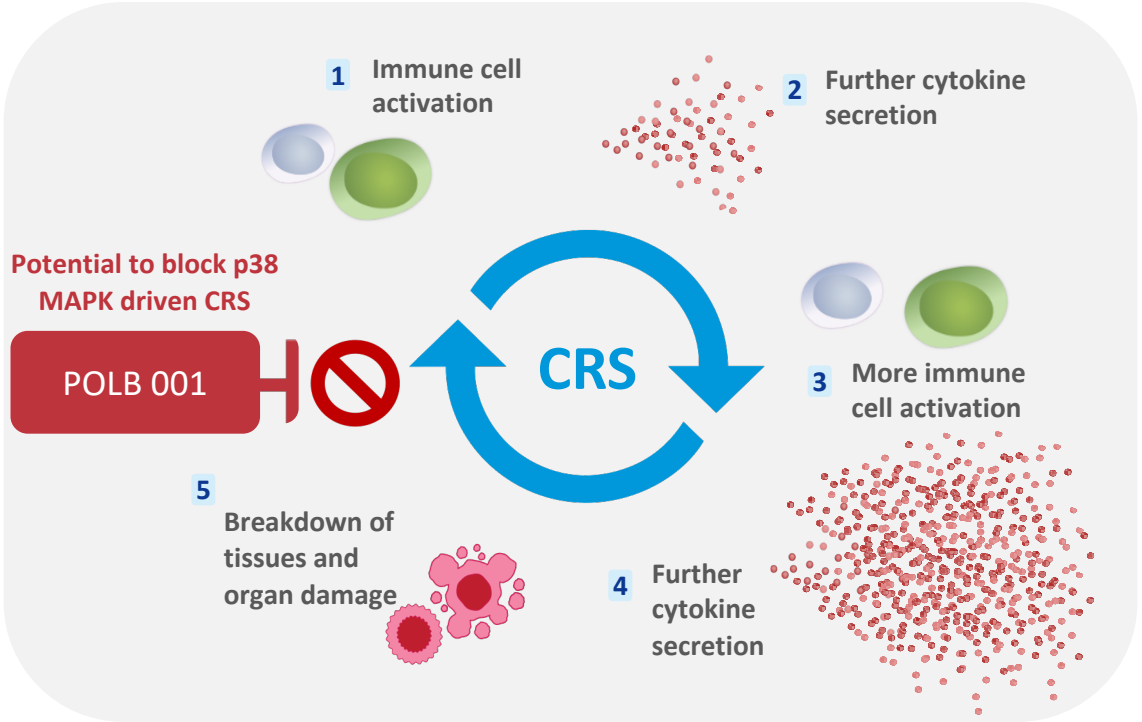
Severe influenza
Severe influenza infections can cause hypercytokinaemia, also known as CRS

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

Cell therapy
New generation cancer therapies such as CAR T 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 - a Potent and Selective Inhibitor of p38 MAPK Signaling

Strong potential treatment for acute inflammatory conditions including severe influenza & oncology

POLB 001 was widely distributed, inhibited p38 MAPK activation and signaling and reduced the inflammatory response following Phase Ib LPS challenge

Target inhibition confirmed

- p38 MAPK phosphorylation in CD14+ monocytes was significantly reduced across all active treatment groups

Demonstrated potent reduction of key inflammatory markers associated with CRS and severe influenza

- The typical LPS-induced rise in plasma cytokine levels (**TNF-α, IL-6**, and **IL-8**) decreased between 56-81% across all cytokines in subjects treated with 70 mg or 150 mg POLB 001 twice daily

Clear dose response relationship observed

- Dose-proportional PK profile at dose range of 30 – 150mg BID; parameters were in line with previous Phase I MAD and SAD studies

Well tolerated across all doses with no serious adverse events reported

- The highest number of AEs were observed in the placebo group with headache being the most commonly reported event

Partnering

- Engaging in discussions with potential partners for out-licensing of POLB 001, CSR and data room is available for review under CDA

CRS Drivers: Oncology Treatments

Toxicities such as CRS are a challenge in the clinic

- Up to 95% of CAR T cell patients suffer CRS related side effects & this side effect is experienced across multiple other oncology modalities
- Severe cases of CRS are life-threatening and may require intensive supportive care, including mechanical ventilation - adding additional strain to healthcare systems
- Advancements in cancer immunotherapy is driving demand for effective CRS treatments
- A number of potential partners have highlighted their interest in a treatment for CRS associated with oncology treatments
- **Clinical trial enabling activities to advance POLB 001 in oncology are ongoing**

Artificial Intelligence Programmes

Unlocking insights from unique human challenge trial data

Influenza

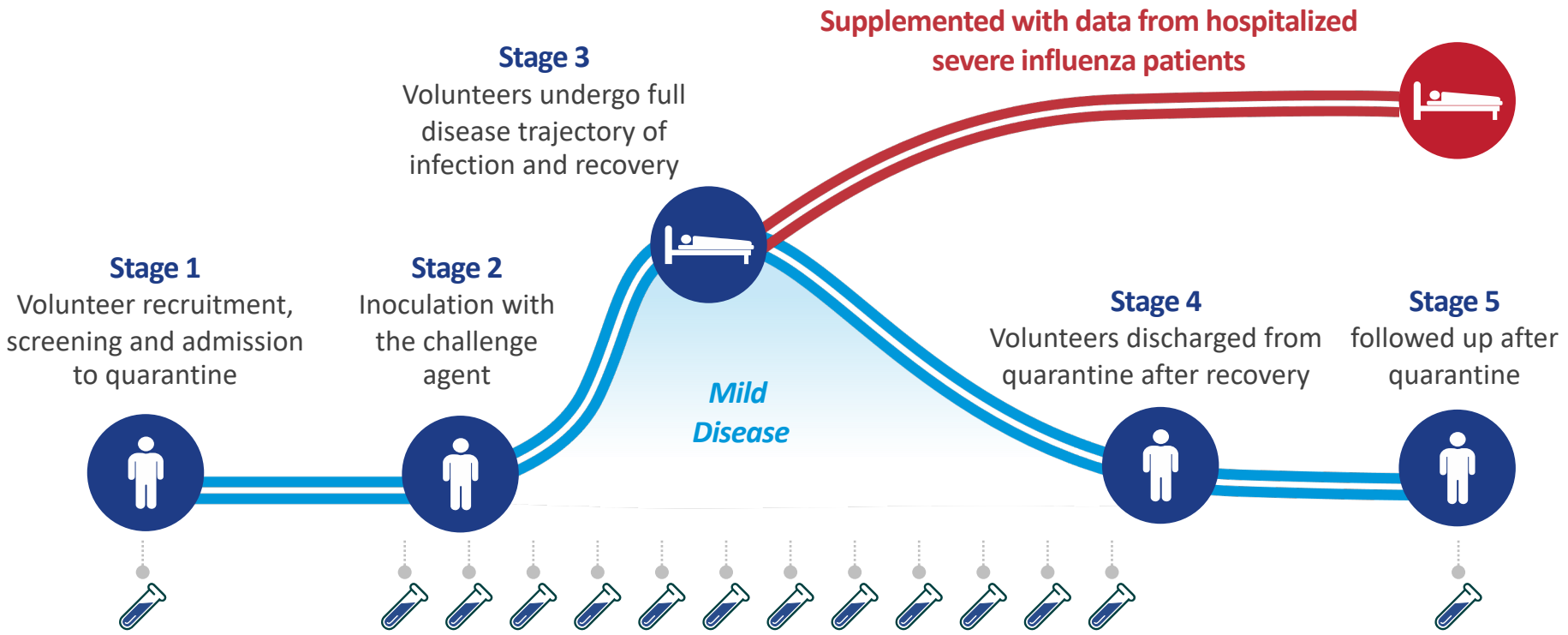
RSV

Unique Human Challenge Trial Data

High quality data enables training of cutting-edge AI algorithms leading to higher quality outputs

nature 19 September 2023

AI can help to speed up drug discovery – but only if we give it the right data



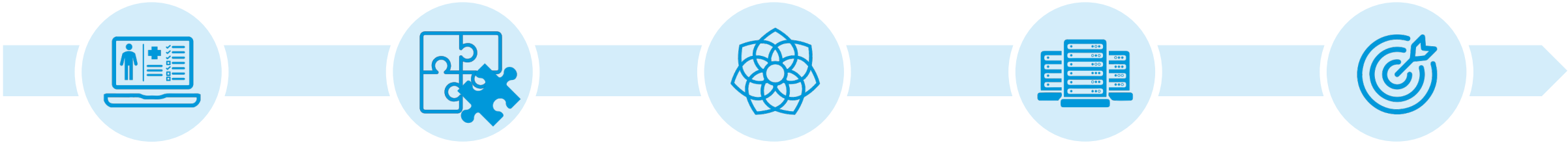
Large number of samples taken from volunteers over longer period when compared to hospital patient data
6Gb of data per volunteer

Benefits of Challenge Data

- **Multi-parametric dataset – clinical, biological and digital**
- **Known infection time and dose**
- **Clean data – maximised signal, minimized noise**
- **Verifiable clinical assessment – Controlled environment**

Industry Leading Human Challenge Trial Data to Power AI-Led Drug Discovery

Extensive database suitable for computational ingestion



High Quality and Unique Challenge Trial Data

Supplemented with Public Datasets

To Build Unique Disease AI Models

In Depth Analysis

Novel Drug Targets and Treatments

Two AI programmes with world leading specialists

*AI analysis of **Influenza** data*

CytoReason

"Human challenge data is extremely rare, and the number of such datasets is limited. None of them have the same richness as this dataset"
Prof Shai Shen-Orr, Co-Founder & Chief Scientist

*AI analysis of **RSV** data*

ONETHREE BIOTECH

"One thing I was excited about was the uniqueness and quality of the data. AI is only as powerful as the data you bring in"
Neel Madhukar, PhD, CEO

OneThree Biotech – Clinically Validated AI Platform

New RSV drug targets & treatments identified for Poolbeg

Poolbeg's Partnership with OneThree Biotech

- ATLANTIS AI platform analysed RSV Human Challenge Trial data
- The first time RSV human challenge trial data was analysed using AI - and successfully identified candidate drugs
- Drugs identified will ameliorate the symptoms of RSV infection, and have not previously been investigated in the context of viral infection
- Prioritised drugs with existing Phase I safety data to reduce spend and risk that Poolbeg can licence
- **Lab based validation expected to be completed H2 2024**
- **Partnering ready**

OneThree Biotech's Partners

AstraZeneca

Boehringer Ingelheim

LEO

Stanford University

RSV (Annual)

- #1 cause of hospitalization in infants
- 120k+ deaths in children under five years
- 177k hospitalizations in US with 4k deaths (65+ years)
- Annual cost of hospitalizations in US adults aged ≥50 years exceeding $1bn

CytoReason – World Leader in AI Driven Drug Development

Multiple novel influenza drug targets identified

Poolbeg's Partnership with CytoReason

- Advanced AI platform can analyse multi-omic datasets to identify which immune cells are responsible for blocking disease and aiding recovery
- Multiple novel drug targets for influenza identified
- Unparalleled insights into disease generated
- Actively exploring the most effective way to further develop the novel drug targets in order to generate value
- **Progressing towards drug target validation - expected to complete in 2024**
- **Partnering ready**

CytoReason's Partners

Pfizer

Roche

sanofi

MERCK

Influenza (Annual Global)

- More than 1 billion cases
- 5-10m hospitalisations
- >500k influenza related respiratory deaths

Oral Delivery Platforms

Utilising validated delivery technology to develop:

- **Metabolic Conditions: Oral GLP-1 Agonist**
- **Oral Vaccines**

Oral Platform: Metabolic Conditions

Tapping into large addressable markets

- Oral encapsulation technology licence for metabolic disease treatments (such as pre-diabetes, diabetes, obesity)
- Preparing a proof-of-technology clinical trial to determine that a Glucagon-like Peptide 1 receptor (GLP-1) agonist can be successfully delivered orally in humans
- **Oral GLP-1 agonist trial expected to commence H1 2024**
- Partnered with **Nasdaq listed biopharma** to produce a prototype oral drug for a metabolic condition, potential to expand to a full licensing agreement
- Opportunity to do other similar deals

Metabolic Diseases – A Fast Growing Market

- >500m diabetes sufferers globally
- >1bn obese people globally
- GLP-1 agonist market expected to exceed $150bn by 2031

Developing the Next Generation of Vaccines using Oral Delivery

Targeted oral delivery

- Exclusive licence to encapsulation technology
- Developing a platform for the encapsulation of vaccines for a wide range of diseases, representing a significant commercial opportunity
- Oral vaccines can trigger "mucosal immunity" in the gut and respiratory system, protecting against infectious threats in those areas and preventing transmission and growth of disease-causing pathogens

- **Non-dilutive funding secured** - The EncOVac Consortium, led by Poolbeg, received funding to support the development of a Phase I clinical trial ready oral vaccine candidate under the Irish Government's Disruptive Technologies Innovation Fund (DTIF)
- **Encapsulation validation phase to complete H2 2023**

The Poolbeg led EncOVac Consortium

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Business model and Investment case

Model for Generating Sustainable Shareholder Value

Rapidly developing assets using a unique capital light approach

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

→ **Excellent progress being made across the portfolio**

Global Pharma's Partnering Appetite Remains High

Pharma and biotech companies seeking to replenish their drug pipelines and defend against pending patent cliff

Select Infectious Disease Deals

Pfizer acquired ReViral
up to $525m, April 2022, *RSV*

Bavarian Nordic acquires vaccines from Emergent
$270m upfront + $110m milestones,
February 2023

Select Metabolic Disease Deals

Novo Nordisk acquired Inversago Pharma to develop new therapies for obesity, diabetes and other serious metabolic diseases
Up to $1.075b deal, Aug 2023

Eli Lilly and Nimbus enter metabolic diseases deal
$496m in funding and milestone payments,
Oct 2022

Investment Case

Well positioned to create sustainable shareholder value into the future

Team with Exceptional & Proven Track Record

Targeting Large Addressable Markets

Unique Model & Well Capitalised

Multiple Near Term Value Inflection Points

H2 2023	Oral Vaccine Programme – Encapsulation Validation
H2 2023	RSV AI programme – lab-based validation
2023	POLB 001 Oncology clinical trial enabling activities, progressing towards initiation in 2024
2024	Influenza AI programme – lab-based target validation
2024	Oral GLP-1 agonist trial commencement
Ongoing	Monetisation / partnering for POLB 001, AI programmes & potentially other assets


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Questions


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Appendices

The Origins of POLB 001

High quality and unique human data samples used

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 impressive pre-clinical and Phase I data POLB 001 was chosen as the best candidate and in-licensed

Accelerated Timeline (10 - 15 months)

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

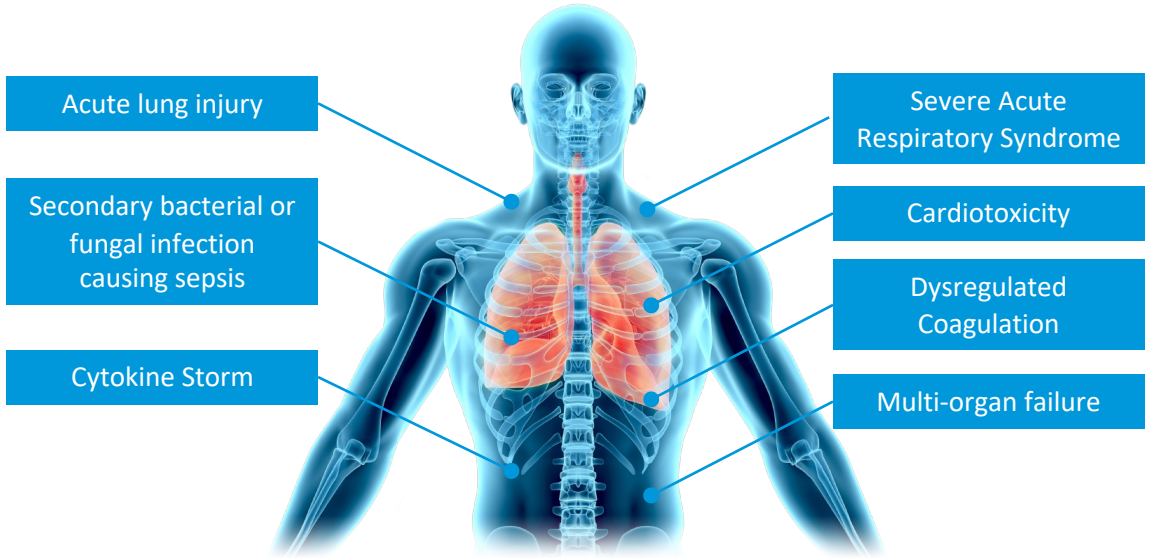
CRS Drivers: Severe Influenza

Dampening the body's hyperinflammatory response

What separates POLB 001 from other influenza treatments

- **Unaffected by Viral Strain or Variants**
- **Controls Tissue-Damaging Cytokines**
- **Preserving Immune Function**
- **Enabling Influenza Treatment Beyond the 48-Hour Window**
- **Shelf stable oral drug – ideal for stockpiling**

Severe Influenza Can Cause Life Changing Injuries And Death



No currently approved therapy

Significant unaddressed market potential (Annual)

3-5 Million
Severe influenza cases **globally**

$2 Billion
Anti-viral market by 2025
(estimated)

$11 Billion
Economic burden in the **U.S.**
(estimated)

500k+
Influenza-related respiratory deaths

LPS Human Challenge Trial

Robust positive clinical data generated – successfully met all clinical endpoints

What is LPS?

- A bacterial product that mimics infection activating the immune system
- Can drive both local and systemic inflammation typical of a cytokine storm
- One step removed from the infected critical care patient

Trial Design

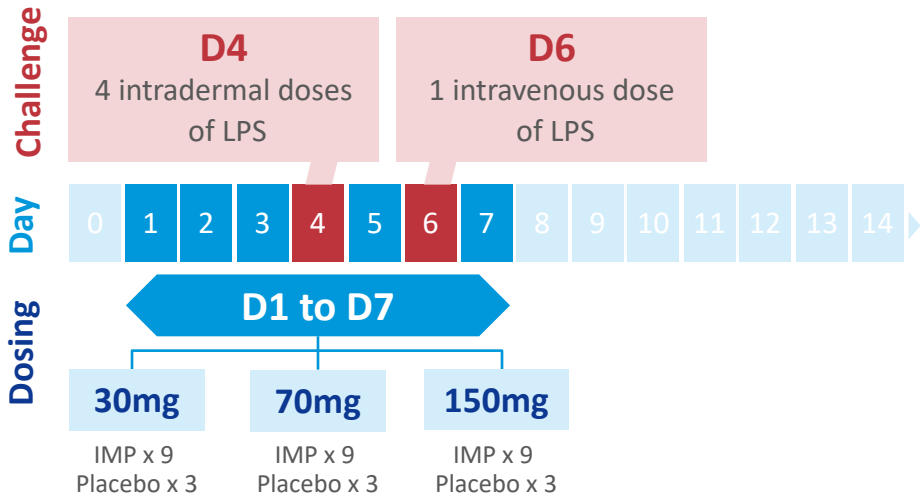
- Randomised, double-blind, placebo-controlled, multiple dose, inflammatory challenge trial in healthy volunteers
- Three cohorts with escalating dose, 12 volunteers per cohort
- POLB 001 or placebo dosed orally, twice daily for 7 consecutive days

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

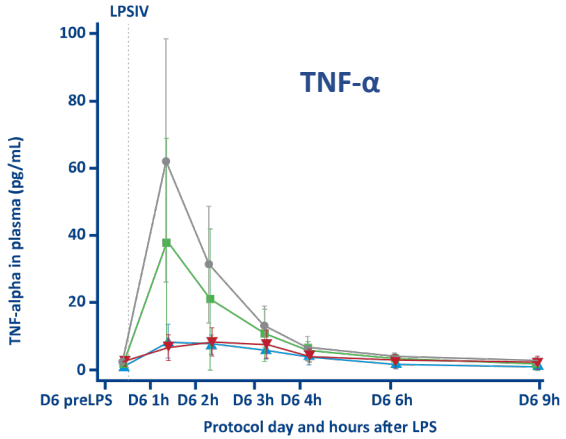
- Skin response by imaging
- Blister exudate analysis
- Skin punch biopsy
- Safety & tolerability

Intravenous LPS challenge

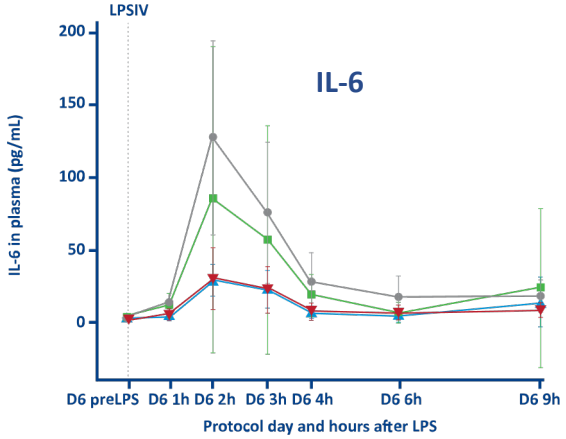
- Bloods (cytokines, vascular markers, CRP)
- *Ex-vivo* LPS response
- Safety & tolerability (inc. vital signs, AE's, ECG, Haematology)

LPS Human Challenge Trial Results

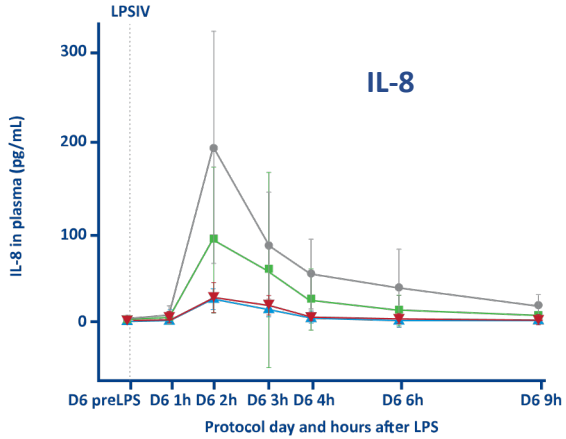
POLB 001 induced significant reductions across several key p38 MAPK driven cytokines



TNF-α reduction of **73.5% and 56.2%** seen for **70 mg and 150 mg doses respectively** (p = 0.0003†)



IL-6 reduction of **57.4% and 63.5%** seen for **70 mg and 150 mg doses respectively** (p = 0.0002†)



IL-8 reduction of **80.7% and 76.7%** seen for **70 mg and 150 mg doses respectively** (p < 0.0001†)

- Placebo
- 30 mg POLB001
- 70 mg POLB001
- 150 mg POLB001

TNF-α, IL-6 and IL-8 levels decreased between 56-81% in subjects treated with 70 mg or 150 mg POLB 001 twice daily

Systemic inflammatory response

- Significant, dose-dependent reduction was observed in the LPS-driven IL-6 response in plasma for active treatments compared to placebo
- Significant reduction in IL-8 and TNF-α in plasma was observed for all active treatments compared to placebo
- For IL-10, a significant reduction was observed for POLB 001 70mg and 150mg compared to placebo

†The exploratory analysis suggested statistically significant improvement in treatment (p<0.05) for the endpoints examined.
CRS = cytokine release syndrome; LLOQ = Lower limit of quantification ; IL = interleukin; IV = intravenous; LPS = lipopolysaccharide.

OneThree Biotech – Clinically Validated AI

Novel treatments for RSV

Neel S Madhukar, PhD
Co-Founder & CEO

Coryandar Gilvary, PhD
Co-Founder & Chief Scientist

Oliver Elemento, PhD
Co-Founder & VP Biology

Identifying disease targets from which drug candidates can be explored

- Integrated database with data mapping and ingestion pipeline linking thousands of data sources
- Drug efficacies, post-treatment transcriptional responses, drug structures, reported adverse events, bioassay results, and known targets used to predict drug-target interactions

Predicting drug-target interactions

Datasets

- **National Cancer Institute's Development Therapeutics Program (NCI-DTP)**
  Effect of **drug modulation for over 20,000 compounds** was ingested to understand the response profiles of various tissues and cell lines
- **Broad Connectivity Map (CMap)**
  A public library of over 1.5M **gene expression profiles** from c. 5,000 small molecule drugs and genetic reagents.
- **SIDER Database**
  Platform which has digitalized, and formatted **side effects of drugs** based on information recorded on the labels of each approved drug
- **PubChem and Drug Bank**
  All **bioassay results** and chemical structures were downloaded to provided further data on the relationship between compound structure and biochemical effects.

671 Data Types	**800K** Clinical Trials	**116K** Samples	**190M** Compounds
280M Publications	**9K** Diseases	**71B** Database rows	**32M** Experiments

Benefits of Oral Delivery

Potential application across numerous therapeutic areas

Innovative solutions

- Adaptable technology to tailor release in specific gut regions
- Natural biodegradability using a food-grade encapsulation platform
- Protect from stomach digestion

Mass access to treatment

- Easier to administer than an injection
- Reduced need for trained staff
- No needle phobia or biohazard waste
- People are more willing to take an oral product

Manufacturing & distribution

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

POLB 002 – Respiratory Virus Infection Immunotherapy

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

Overview

- 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
- US & European patents granted & continuing to expand

Respiratory Virus Infections

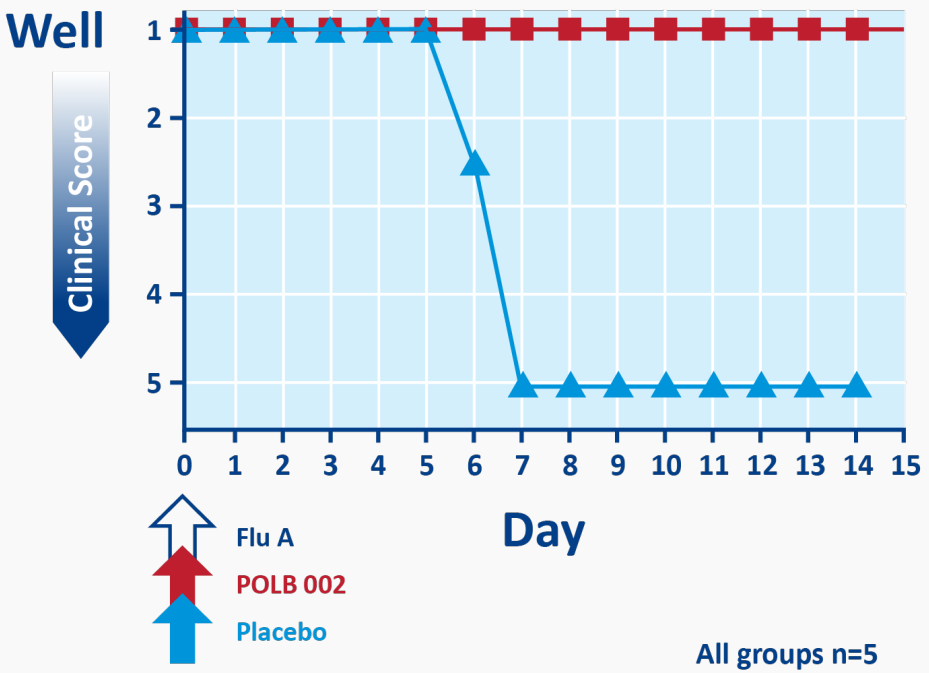
5-20%
Global population infected by seasonal outbreaks

3M+
Annual deaths worldwide

Top 5
Global cause of death

In vivo influenza A challenge

- Late preclinical stage with extensive preclinical data package
- No reduction in efficacy or safety issues after repeat dosing



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

POLB 003 – Melioidosis Vaccine Candidate

Late preclinical stage

Overview

- *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
- CDC Designated Biothreat – stockpiling potential
- Global warming expected to change melioidosis epidemiology

Melioidosis

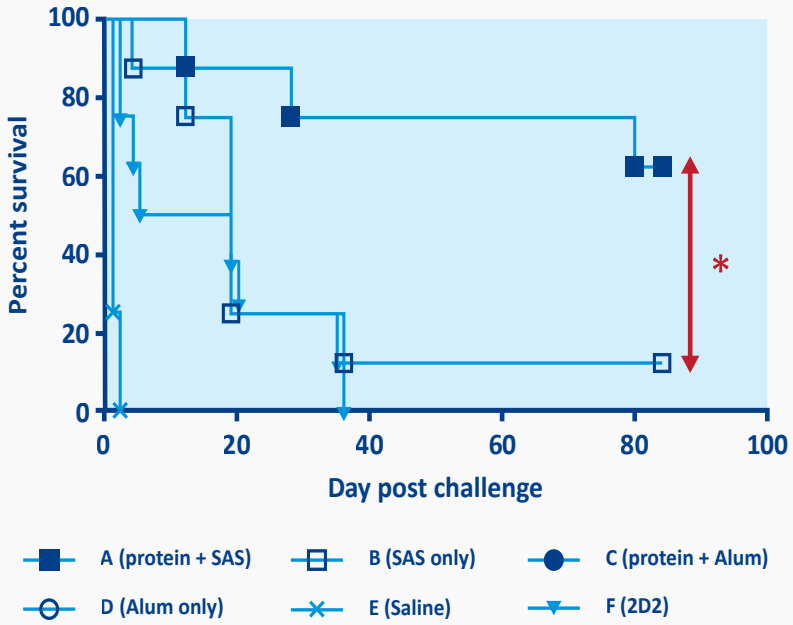
165,000
Estimated global cases per annum

54%
Of cases are fatal

0
Vaccines available

Significantly enhances survival in a model of chronic melioidosis

- Late preclinical stage with extensive preclinical data package



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.

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