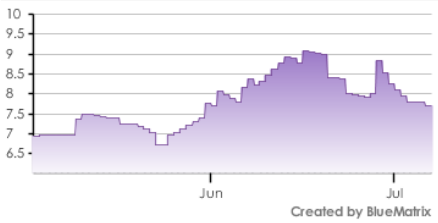
POOLBEG PHARMA LTD (LON:POLB)

November 2, 2023

Pharmaceuticals, Biotechnology & Life Sciences

52-WEEK HIGH	**11.14p**
52-WEEK LOW	**6.18p**
PRICE	**6.88p**
MARKET CAP MLN	£34.40

Share Price



Major Shareholders

Cathal Friel 7.28%	
Shroders PLC 4.99%	
Michael Kelly 3.63%	
Shares in issue	500,000,000
Avg Three-month trading volume	762,119
Primary index	AIM
Next Key Announcement	2023 financial results in April/May

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Driving forward R&D programmes while seeking partners

Accelerating R&D and partnerships

Poolbeg Pharma continues to advance its lead programmes and has struck a collaboration that may lead to its first out-licensing deal. The company is also continuing its campaign to find a partner and effectively monetise its phase II-ready lead compound POLB 001, which they are expanding into oncology, while progressing its other assets towards the clinic.

In recent months, Poolbeg has established an initial partnership for its exclusively licensed oral drug delivery technology, strengthened the patent protection on POLB-001, obtained the initial outputs from its influenza AI-based drug discovery programme and commenced lab-based validation of drug targets identified during its RSV AI programme.

Poolbeg has formed a collaboration with an undisclosed Nasdaq-listed biopharma company to evaluate a drug formulation using its oral drug delivery technology. The aim is to optimise the delivery of the partner company's novel drug to its target location for use in a metabolic condition, with the hope that this could improve efficacy and potentially value. Management hopes this will develop into a full licensing agreement, which could potentially generate some early revenue.

This partnership reflects recognition of the oral delivery technology's benefits and management expects that it could lead to other similar arrangements in the future, given the broad applicability of the technology particularly in metabolic disease. Poolbeg is already evaluating the technology for the oral delivery of a glucon-like peptide 1 (GLP-1) agonist, which we presume to be liraglutide. This product is approved as an injectable for obesity and diabetes.

A proof of technology study on this product is due to commence in H1 2024, after which Poolbeg may try to find a licensing partner. The global GLP-1 market has been predicted to rise rapidly to c.$70bln by 2032. Although there are a number of oral formulations of GLP-1 agonists in clinical development, including with liraglutide, Poolbeg believes it can achieve higher oral bioavailability with its technology.

Poolbeg is progressing towards validation of the outputs from its AI-led programme with CytoReason. This programme combined Poolbeg's influenza disease progression data from human challenge trials with CytoReason's AI-led platform and has enabled the identification of a number of novel drug targets for influenza. The company's Scientific Advisory Board recently reviewed the outputs from the programme and reached a consensus on the prioritisation of novel drug targets to bring forward to validation. This is due to be completed in 2024, and Poolbeg is continuing to discuss the outputs from this programme with prospective partners.

Cash of £14mln

Poolbeg reported cash of £14.1mln as of the end of June 2023, down from £16.2mln as of December 2022. The company posted an H1 loss of £1.8mln, including £0.9mln of R&D expenditure, £1.4mln of admin expenses and £0.5mln of other income.

The cash position coupled with a number of recent milestones should allow Poolbeg to advance its leading programmes and help the company on the way to realising early revenues.

Chief Executive Officer: Jeremy Skillington, PhD, has had an extensive career in biotechnology across companies such as Genentech, Opsona Therapeutics, TriMod Therapeutics and HS Lifesciences. Jeremy joined Inflazome upon its founding in 2016 and played a key role in their acquisition by Roche in September 2020 for €380mln upfront, among other milestones.

Chairman: Cathal Friel is co-founder and chairman of hVIVO plc; he was also co-founder of Amryt Pharma which was sold in 2023 for $1.48bln. Prior to that he was founder of Fastnet Oil & Gas and co-fouder of Merrion Stockbrokers.

POLB 001 status

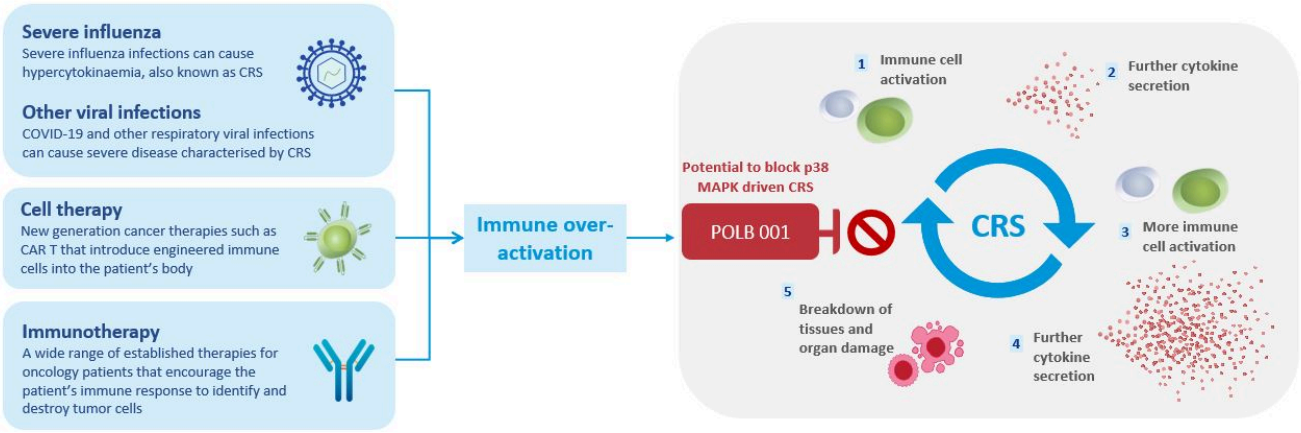
POLB 001 is a small molecule immunomodulator targeting Cytokine Release Syndrome (CRS) experience in severe influenza and other acute inflammatory conditions. The most recent data from the LPS challenge study earlier this year showed that it effectively reduces multiple inflammatory cytokines in a dose-dependent manner and has a good safety profile. Based on WHO data, Poolbeg estimates there may be 3-5mln severe influenza cases a year globally. The company has been granted patents in the US and Europe out to 2038.

The opposition hearing scheduled by the European Patent Office relating to a challenge to the company's European patent (Immunomodulator I), was withdrawn in September 2023. This has now favourably concluded this matter with the patent maintained as granted. Immunomodulators I and II cover the use of P38 MAP kinase inhibitors for treatment of severe influenza and hypercytokinaemia — the uncontrolled and excessive release of pro-inflammatory signaling molecules (cytokines) that causes severe adverse physiological effects.

The company has a worldwide license to IP covering POLB 001 for all uses, but is expanding this IP protection to cover the use of p38 MAP kinase inhibitor class including for uses in oncology. In particular, it could be used to mitigate CRS, a common side effect to some oncology treatments, particularly CAR T cell therapy where it is seen in up to 95% of treatments. The most severe cases are life-threatening and can require intensive care support.

Poolbeg recently noted that as a result of its discussions with prospective partners, it is actively exploring a potential new indication for POLB 001 in oncology beyond CAR T. This could open up a further market for POLB 001. Development towards a clinical trial to advance POLB 001 in oncology is ongoing. Company partnering discussions about this molecule are ongoing.

Exhibit 1 - Cytokine Release Syndrome mechanism



Source: Poolbeg Investor Presentation

AI-assisted development

Poolbeg has collaborated with CytoReason and OneThree Biotech to utilise the companies' AI technologies to identify novel drug targets and treatments for influenza and Respiratory Syncytial Virus (RSV), respectively.

Lab-based validation is ongoing and management expects outputs for the RSV programme later this year, with the commencement of the influenza programme in 2024. The AI-led approach to drug discovery could enable faster and lower cost identification of drug targets, reducing risk and increasing likelihood of success.

Oral delivery platform

Poolbeg's oral delivery platform aims to target markets for vaccine delivery and the treatment of metabolic diseases using its licensed and validated encapsulation technology. These could be important markets for generating early revenue.

The EncOVac consortium, led by Poolbeg, was awarded €2.3mln in non-dilutive grant funding (which does not contribute to year-end cash figure) from the Irish government and has moved into the encapsulation validation phase. Management expects this to be completed in H2 2023. This technology platform covers multiple infectious diseases and could be an important commercial opportunity for the company.

The company's GLP-1 agonist for the treatment of metabolic diseases such as diabetes and obesity is progressing towards a proof-of-technology exploratory study to show that it can be delivered orally in humans. The trial is due to commence in H1 2024.

Exhibit 2 - Poolbeg product pipeline

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)

Source: Poolbeg investor presentation

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