Poolbeg Pharma plc

Results for the year ended 31 December 2023

Significant pipeline advancements

Strategic expansion into cancer immunotherapy-induced CRS unlocking a market opportunity exceeding US$10Bn

Key senior management hires

30 April 2024 - Poolbeg Pharma (AIM: POLB, OTCQB: POLBF, 'Poolbeg' or the 'Company'), a biopharmaceutical company focussed on the development and commercialisation of innovative medicines targeting diseases with a high unmet medical need, announces its audited results for the year ended 31 December 2023.

Financial & Corporate Highlights

- Cash balance of £12.2 million as at 31 December 2023
- Industry veteran, Professor Brendan Buckley, appointed as Non-Executive Director
- Recruitment of key management hires, former executives of Amryt Pharma plc, a rare disease company that was acquired by Chiesi Farmaceutica for US$1.48 billion

Operational Highlights

- Positive results from POLB 001 LPS human challenge trial revealed potent target inhibition and major reductions in key inflammatory markers
- Strategic expansion of POLB 001 as a preventative therapy for cancer immunotherapy-induced Cytokine Release Syndrome (CRS)
- POLB 001 patent portfolio strengthened with new patent filings and grants
- Positive conclusion to the Immunomodulator I patent opposition with the opposition withdrawn
- Multiple novel influenza drug targets identified as part of Artificial Intelligence (AI) led programme with the prioritised targets endorsed by Poolbeg's Scientific Advisory Board
- Positive outputs from the lab-based analysis and successful prioritisation of the Respiratory Syncytial Virus ('RSV') treatment candidates identified as part of AI-led programme
- Signed a strategic collaboration agreement with a Nasdaq listed biopharma company for the development of an optimised oral drug to treat a metabolic condition
- POLB 001 data presented at 65th American Society of Hematology (ASH) Annual Meeting and Exposition and the 18th International Congress of Immunology (IUIS), and garnered interest from global industry leaders in the field of bispecific antibodies and CAR T cell therapies
- The Company engaged with a number of Key Opinion Leaders (KOLs) to refine the clinical trial design for its oral GLP-1R programme and is working towards commencement of its proof-of-technology clinical trial in 2024

Post Period End

- Positive *in vivo* data confirmed POLB 001's efficacy in reducing cancer immunotherapy-induced CRS in an animal model, strengthening and facilitating the expansion of patent applications for POLB 001 in cancer immunotherapy-induced CRS
- Independent Advisory Board of Key Opinion Leaders, healthcare payers and clinical trial experts, were supportive of POLB 001's potential to both prevent and treat cancer immunotherapy-induced CRS

- Independent research confirmed a market opportunity exceeding US$10 billion[1] for POLB 001 as an orally delivered preventative therapy for cancer immunotherapy-induced CRS
- Cathal Friel, Co-Founder and significant shareholder, assumed the role of Executive Chairman

Jeremy Skillington, PhD, Chief Executive Officer of Poolbeg Pharma, commented: *"We made excellent progress and hit multiple key milestones in 2023, the most important of all perhaps was filing patent applications which will give us international protection over the use of POLB 001 as a preventative therapy for cancer immunotherapy-induced CRS, in addition to the existing severe influenza indication. With a market opportunity exceeding US$10 billion in cancer immunotherapy-induced CRS, positive data generated, and a robust patent portfolio - POLB 001 has great potential to generate significant value for shareholders.*

"Our disciplined approach to capital allocation has ensured that we have maintained a robust cash position. We remain focussed and are getting good engagement on partnering to maximise the value of our in-house programmes. Poolbeg has the expertise to succeed in our strategy of developing, partnering and commercialising innovative medicines to generate near-term revenues with a goal to achieve sustainable profitability.

"Going forward, I believe we are well positioned to generate value for our shareholders, while addressing significant unmet medical needs across multiple disease areas."

Investor presentation
Poolbeg's management team will provide a live presentation via the Investor Meet Company platform on **Tuesday 30 April 2024 at 6pm BST.**

The presentation is open to analysts and investors, those who already follow Poolbeg on the Investor Meet Company platform will automatically be invited. Investors can sign up to Investor Meet for free and add Poolbeg Pharma plc to their company dashboard here.

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About Poolbeg Pharma

Poolbeg Pharma plc is committed to the development and commercialisation of innovative medicines targeting diseases with a high unmet medical need, with a growing emphasis on rare and orphan diseases. Its model focusses upon developing its exciting clinical assets and commercialising approved and marketed drugs to support the growth of the Company and the development of its robust pipeline of innovative products, thereby driving significant value creation.

Poolbeg is led by an experienced leadership team with a history of delivering significant shareholder value. The team has been strengthened by the appointment of three former members of the Amryt Pharma plc leadership team, with the intention of repeating Amryt's success and generating near term revenues.

Poolbeg's clinical programmes target large addressable markets including cancer immunotherapy-induced CRS, infectious disease, and metabolic conditions such as obesity with the development of an oral GLP-1R agonist. It uses a cost-effective development philosophy to generate high quality human data to support partnering and further development. Its AI-led infectious disease programmes analyse unique data from human challenge trials to identify clinically relevant drug targets and treatments, leading to faster development and greater commercial appeal.

For more information, please go to www.poolbegpharma.com or follow us on Twitter and LinkedIn @PoolbegPharma.

Forward-Looking Statements

This announcement may contain forward-looking statements and the words "expect", "anticipate", "intends", "plan", "estimate", "aim", "forecast", "project" and similar expressions (or their negative) identify certain of these forward-looking statements. The forward-looking statements in this announcement are based on numerous assumptions and Poolbeg's present and future business strategies and the environment in which Poolbeg expects to operate in the future. Forward-looking statements involve inherent known and unknown risks, uncertainties and contingencies because they relate to events and depend on circumstances that may or may not occur in the future and may cause the actual results, performance or achievements to be materially different from those expressed or implied by such forward-looking statements. These statements are not guarantees of future performance or the ability to identify and consummate investments. Many of these risks and uncertainties relate to factors that are beyond Poolbeg's ability to control or estimate precisely, such as future market conditions, currency fluctuations, the behaviour of other market participants, the outcome of clinical trials, the actions of regulators and other factors such as Poolbeg's ability to obtain financing, changes in the political, social and regulatory framework in which Poolbeg operates or in economic, technological or consumer trends or conditions. Past performance should not be taken as an indication or guarantee of future results, and no representation or warranty, express or implied, is made regarding future performance. No person is under any obligation to update or keep current the information contained in this announcement or to provide the recipient of it with access to any additional relevant information.

Chairman's Statement

Dear Shareholder,

I am pleased to present Poolbeg Pharma plc's ("Poolbeg") annual report and financial statements for the year ended 31 December 2023.

Overview

Poolbeg made significant strides in 2023, both in advancing our pipeline of high value programmes and enhancing our corporate structure. We welcomed several key industry leaders to our team, each bringing a proven track record of delivering significant shareholder value.

At Poolbeg, we are committed to the development and commercialisation of innovative medicines targeting diseases with a high unmet medical need, with a growing emphasis on rare and orphan diseases. Our model focusses upon developing and partnering our exciting R&D programmes and commercialising approved and marketed drugs to support the growth of the Company and the development of our robust pipeline of innovative products, thereby driving value for the Company and its shareholders.

Positive corporate developments & industry leading team

I co-founded Amryt Pharma plc ('Amryt'), the rare disease company, in 2015, and in the years that followed, Amryt experienced rapid growth, driving sales revenue to more than US$261 million[2] prior to its ultimate sale in 2023 for US$1.48 billion[3]. In November 2023, Poolbeg announced the appointment of key former executives of Amryt to our leadership team:

- **David Allmond, Chief Business Officer**, previously Chief Business Officer at Amryt, where he was instrumental in putting in place the global commercial infrastructure which supported its revenue growth from c. US$1.5 million[4] when he joined in 2016, to over US$261 million some six years later. David played a pivotal role in acquiring both products and companies at Amryt.
- **John McEvoy, SVP, Chief Legal Officer,** was Global General Counsel at Amryt from 2017 to 2023 where he played a pivotal role in Amryt's rapid growth, leading multiple acquisitions as well as the company's dual-listing on Nasdaq in 2020 and its subsequent sale to Chiesi in 2023. John is a qualified lawyer in the US (New York), England & Wales, and Ireland.
- **Laura Maher, VP Clinical Operations,** was Associate Director of Clinical Operations at Amryt from 2018, where she led the clinical research programmes for multiple products in Amryt's pipeline including Filsuvez®, the world's first approved epidermolysis bullosa treatment. Laura has an extensive background in clinical operations.

Poolbeg intends to follow a similar strategic approach to Amryt by developing and partnering our existing assets and commercialising approved and marketed drugs thereby driving significant value creation. We welcome these exceptional individuals to the Poolbeg team as we accelerate this strategy.

In May 2023, we also welcomed Professor Brendan Buckley to the Board as a Non-Executive Director. Brendan has over 40 years' experience in clinical practice as a Consultant Physician and has extensive industry experience in the CRO and biopharmaceutical space. Brendan was a member of the Board of Directors of the Irish Medicines Board (now the Health Products Regulatory Authority) and sat on the European Medicines Agency Scientific Advisory Committee on diabetes and metabolism. As we increase our focus on rare and orphan diseases, Brendan's experience as a member of the European Medicines Agency Committee for Orphan Medicinal Products (COMP) provides invaluable insights and greatly benefits the Company.

With POLB 001's strategic expansion into oncology, Poolbeg now has exposure to the high growth rare and orphan drug market

At Poolbeg, we are actively increasing our focus on rare and orphan diseases, leveraging the potential of POLB 001 to address cancer immunotherapy-induced Cytokine Release Syndrome (CRS). We believe that there is potential for POLB 001 to be a rare and orphan therapy because the patients receiving T cell engaging bispecific antibodies and CAR T cell therapy are predominantly suffering from rare or orphan blood (haematological) cancers.

A rare disease is a medical condition that affects a small percentage of the population. In the United States, a rare disease is defined as one that affects fewer than 200,000 people[5] while in the EU, it is characterised as a disease that affects no more than one in 2,000 people[6]. However, definitions can vary by region. Regulatory authorities offer incentives to companies developing orphan drugs, which in the US includes seven years of market exclusivity granted to the sponsor upon marketing authorisation. The orphan drug market is expected to grow more than twice as fast as the non-orphan market[7]. It is expected to grow from US$170 billion in 2023 to US$368 billion by 2030 (11.6% CAGR)[8], with orphan drug sales due to account for 20% of all prescription drug sales by 2026[9]. Our leadership team has significant knowledge and expertise in rare and orphan diseases products, and the Directors believe that Poolbeg is well positioned to benefit from these opportunities.

Strong progress across our pipeline of assets

We made excellent progress in advancing our innovative and attractive pipeline during 2023.

<u>POLB 001</u>

POLB 001 has the potential to be an effective treatment for severe influenza, as well as a breakthrough orally delivered preventative therapy for cancer immunotherapy-induced CRS. The market potential is greater than US$10 billion in the cancer setting alone, according to independent research.

Positive results from our LPS human challenge trial, including a highly significant reduction in p38 MAPK (mitogen-activated protein kinase) driven cytokines, and presentations at key international conferences, including ASH (American Society of Hematology) and IUIS (International Union of Immunological Societies), serve as strong validation for the potential of POLB 001.

We also successfully expanded and enhanced POLB 001's robust intellectual property portfolio.

Post year end, promising *in vivo* animal data were generated which strengthens our belief that POLB 001 has the potential to greatly impact the lives of patients.

<u>AI Programmes</u>

Our two Artificial Intelligence (AI) led programmes with CytoReason and OneThree Biotech achieved key milestones in 2023, yielding unparalleled insights into influenza and Respiratory Syncytial Virus (RSV) through analysis of unique and high-quality human challenge trial data. The global interest in AI-led drug discovery continues to grow, with Big Pharma investing heavily in the space. This approach to drug discovery enables faster target identification, at lower cost and reduced risk. We are actively discussing the exciting outputs from our AI-led drug discovery programmes with prospective partners.

<u>Oral Delivery</u>

In 2023, we also progressed our Oral Glucagon-like Peptide 1 receptor (GLP-1R) agonist programme. We engaged with a number of Key Opinion Leaders (KOLs) to refine the clinical trial design and are working towards the commencement of the proof-of-technology clinical trial. The trial aims to demonstrate successful delivery of an oral GLP-1R agonist in humans and has the potential to tap into a market in obesity and diabetes[10] which is projected to reach US$150 billion by 2031.

Financial

Our disciplined approach to capital allocation has served us well, allowing us to make significant progress across our pipeline of assets while maintaining a robust cash balance. We remain committed to prudent financial management, ensuring that we have the resources necessary to fuel our growth strategy to continue to generate shareholder value.

Poolbeg ended the year with a cash balance of £12.2 million (2022: £16.2 million). The loss for the year amounted to £3.9 million (2022: £4.7 million) and comprises R&D expenses £1.7 million (2022: £2.2 million), administrative expenses £3.4 million (2022: £3.1 million), and tax rebates and other income & charges of £1.1 million (2022: £0.6 million).

Outlook

2023 was an exceptional year for Poolbeg. With our growing focus on the rare and orphan disease space, we are poised to capitalise on the significant opportunities presented by this attractive market. Our lead programme, POLB 001, holds immense promise in addressing unmet medical needs in severe influenza and cancer immunotherapy-induced CRS, with a market opportunity that exceeds US$10 billion in cancer immunotherapy-induced CRS alone. Encouraging discussions have been held with Pharma as they seek solutions for CRS to improve the safety profile and increase the market potential of their therapies. Our experienced team, bolstered by recent key appointments with a track record of success at Amryt, has a wealth of knowledge and expertise to advance our strategy of developing, partnering and commercialising innovative medicines to generate near term revenues with a focus on achieving sustainable profitability.

I assumed the role of Executive Chairman in February 2024 as I strongly believe in the Company's potential, underscored by my recent share purchase. In summary, I am highly optimistic about the potential for Poolbeg to rapidly grow. We have a clear strategic vision and a talented team with a robust cash balance, and a relentless focus on execution. With that in mind, we believe that we are well-positioned to capitalise on the opportunities that lie ahead and deliver long-term value for our shareholders.

Cathal Friel
Executive Chairman
30 April 2024

CEO's Operations Review

I am delighted to report another strong year of progress for Poolbeg Pharma plc. Throughout 2023, Poolbeg made significant progress across our pipeline of assets, achieving key milestones, identifying new markets, and strengthening our intellectual property.

I am particularly proud of the expansion of our lead asset, POLB 001, into cancer immunotherapy-induced Cytokine Release Syndrome (CRS), a move that not only demonstrates our teams' scientific ingenuity but also positions Poolbeg as a leader in responding to this emerging healthcare challenge.

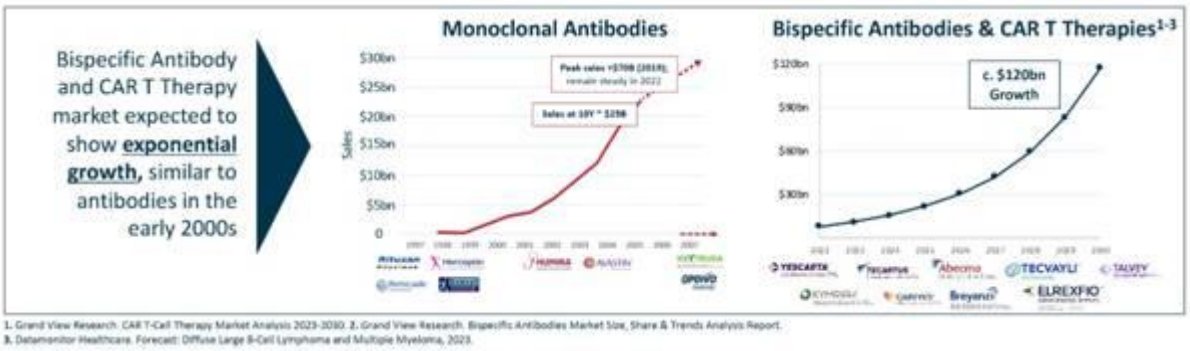
Furthermore, we are pleased to have started 2024 with the addition of a number of key executives to our team, whose expertise and vision will undoubtedly support our ambition of generating near-term revenue with a pathway to profitability. With these developments and our unwavering focus on excellence, I am confident that 2024 holds significant promise for Poolbeg as we continue to drive innovation and deliver value to our shareholders and patients alike.

POLB 001

Strategic expansion of POLB 001 into oncology unlocks a market opportunity exceeding US$10 billion

During 2023, we announced our strategic expansion of POLB 001 into oncology for cancer immunotherapy-induced Cytokine Release Syndrome (CRS), in addition to its potential to treat severe influenza. This strategic decision has unlocked a market opportunity that exceeds US$10 billion. This estimate encompasses solely Multiple Myeloma and Diffuse Large B-Cell Lymphoma due to the rapid advancements in bispecific antibody and CAR T cell therapies for these indications. Cancer immunotherapies are being widely developed across a broader range of haematological malignancies (including many rare or orphan cancers) and solid tumours, which we believe will expand the opportunity for POLB 001 far beyond the estimate of US$10 billion.

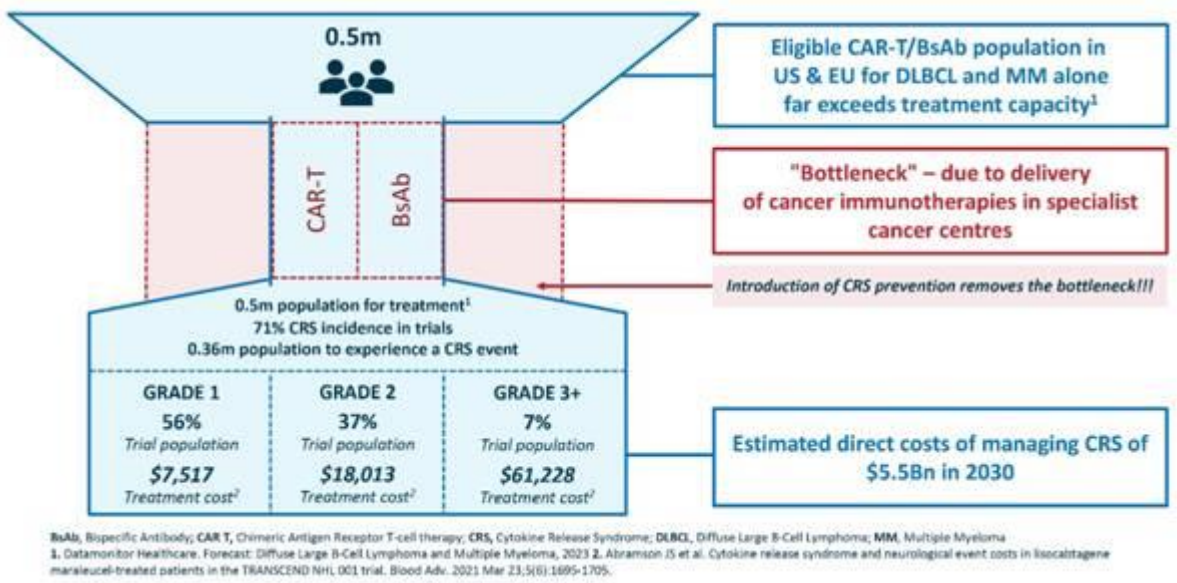
The field of cancer immunotherapy is burgeoning and is predicted to undergo exponential growth in the coming years to US$120 billion by 2030[11],[12],[13].



1. Grand View Research. CAR T-Cell Therapy Market Analysis 2023-2030. 2. Grand View Research. Bispecific Antibodies Market Size, Share & Trends Analysis Report.
3. Datamonitor Healthcare. Forecast: Diffuse Large B-Cell Lymphoma and Multiple Myeloma, 2023.

CRS can occur in >70%[14] of patients treated with T cell engaging bispecific antibodies, or CAR T cell therapy. CRS of any grade can lead to prolonged hospital stays and in some cases mortality risk. The administration of these cancer immunotherapies is therefore restricted only to specialist cancer centres which has created a "bottleneck" in providing seamless, cost-efficient access to these treatments for the patients who need them. This is depicted in the schematic below, where we estimate that by 2030 there will be ~500,000[15] potential eligible patients with Multiple Myeloma (MM) and Diffuse Large B Cell Lymphoma (DLBCL) alone, across the US and EU5. If all of these patients were to be treated with

immunotherapies, the direct costs to the healthcare systems of managing the CRS associated with these immunotherapies would be US$5.5 billion, as illustrated below.



There are currently very few approved therapies for the management of CRS and no approved therapies for the prevention of CRS. As an oral therapy to prevent or treat CRS, POLB 001 has the potential to enable broader use of cancer immunotherapies in an outpatient setting to reduce the risk of a bottleneck occurring, and to make these life-saving therapeutics more readily accessible to patients. However, we believe this may be understated, as immunotherapies are being developed across a much wider range of haematologic cancers and solid tumours and therefore the healthcare budget impact could be much greater. We believe POLB 001 not only has great clinical potential but could also offer a compelling economic case. We are progressing our partnering strategy to accelerate this exciting programme.

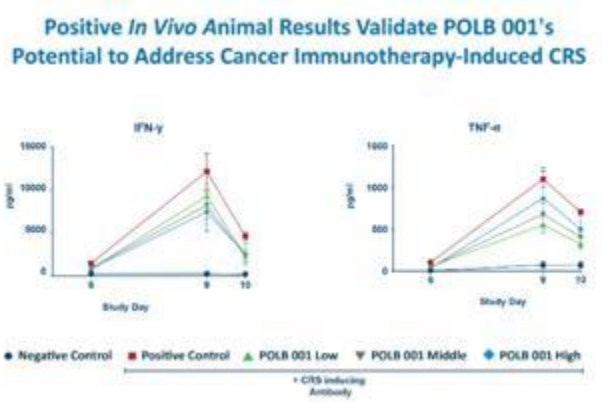
Compelling data generated and presented at world leading scientific conferences

Our confidence in the potential of POLB 001 was strengthened by the positive results from our Phase 1b LPS human challenge trial which showed compelling data, demonstrating a dose dependent reduction of pro-inflammatory cytokines, clinical symptoms, and a strong safety profile following an inflammatory stimulus. The data has highlighted that the drug is well tolerated and attenuates excessive immune responses without completely ablating the immune system, which is particularly important for an immunocompromised patient group such as the patient groups in question for cancer immunotherapy-induced CRS.

Two abstracts showcasing POLB 001 were presented at major international conferences in 2023, representing strong validation of the potential of the drug:

A poster presentation by a clinical leader in Multiple Myeloma (i) releasing further positive data from POLB 001's LPS Challenge Trial and (ii) commenting on its significant potential in cancer immunotherapy-induced CRS was presented at the 65th American Society of Hematology ('ASH') Annual Meeting and Exposition, the world's premier conference focussing on haematological malignancies. The poster presented the potential use of POLB 001 to treat CRS and garnered interest from global leaders in the field of bispecific antibodies and CAR T cell therapies.

An abstract surrounding the positive LPS human challenge trial which highlighted POLB 001's potential as a groundbreaking therapy was presented at the 18th International Congress of Immunology ('IUIS'), the world's leading conference in the field of immunology



Post year end, we received promising *in vivo* results for POLB 001 which demonstrated efficacy in reducing cancer immunotherapy-induced CRS in an animal model. The CRS symptoms significantly improved following administration of POLB 001, with reductions seen in all serum proinflammatory cytokines tested. The data also strengthened and facilitated the expansion of patent applications for POLB 001 in cancer immunotherapy-induced CRS. The product is now Phase 2 ready and there is scientific, clinical and partner interest to advance the programme.

Independent Key Opinion Leaders strongly supportive of POLB 001's significant potential

We also convened an Independent Advisory Board of international Key Opinion Leaders, healthcare payers and clinical trial experts, which endorsed the attractiveness of POLB 001's Target Product Profile (TPP) and its potential as an oral therapy to address the significant unmet medical need in cancer immunotherapy-induced CRS. Contributions from global leaders including Dr Martin Kaiser and Prof Gareth Morgan are highlighted in the figure below.

"CAR T therapy inpatient capacity is a challenge; hence, measures that reduce hospital stay or make treatment mobile are needed."

Lymphoma specialist, UK

"Bispecific antibodies will only be delivered in specialist cancer centres until there is a way to make them safer. POLB 001 could make treatment safe enough to extend bispecifics to a much wider patient population."

Professor Gareth Morgan, US

"The development of an oral CRS preventive therapy will mean no or shorter hospital stays."

Myeloma specialist, FR

"Patients undergoing cancer immunotherapy treatment that suffer with CRS can be critically ill which, alongside a weakened immune system, can further increase their risk of infection."

"Preventing CRS in the first instance would have a significant impact on patient health and wellbeing, as well as reducing the burden on the healthcare system. Current CRS treatments require intravenous infusion, which is difficult to deliver out of hospital, and some can only be used off label in combination with bispecific antibodies."

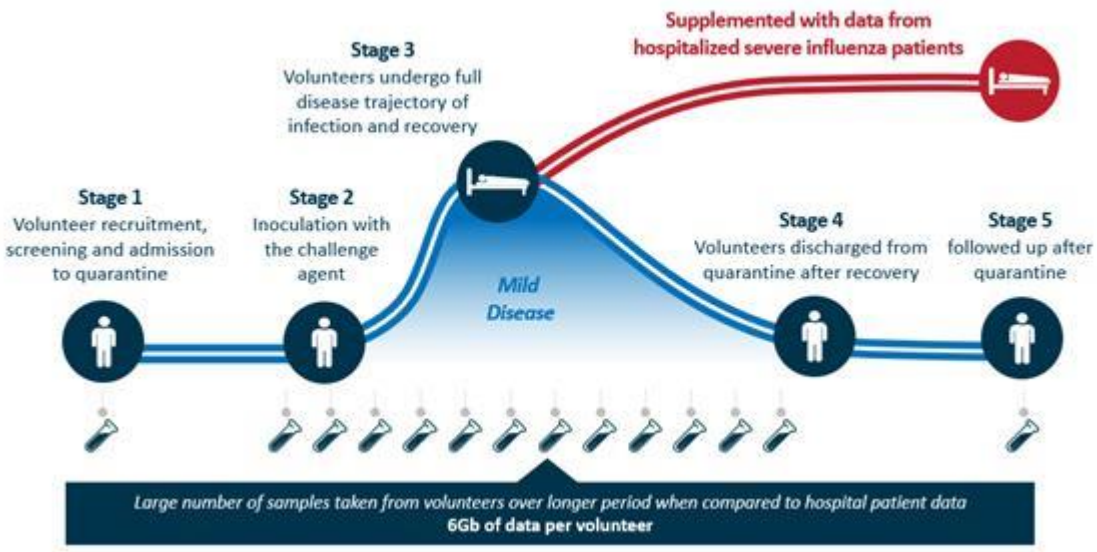
"If there was a therapy that was orally delivered, a whole lot of infrastructure requirement falls away."

Dr Martin Kaiser, Myeloma specialist, UK

Artificial Intelligence (AI) Programmes

Poolbeg has licenced access to a repository of viral human challenge trial data which offers unique insights into human disease. Using Artificial Intelligence to unlock these insights and to discover potential new therapies for patients with respiratory viral conditions has been a key focus of the Company.

Data from human challenge trials are unique in that they track a healthy subject through disease and recovery in carefully controlled and monitored isolation units, collecting samples throughout the course of disease, and vitally collecting matched baseline and follow-up samples before and after infection. This data is unique in the depth of longitudinal virology, health, biomarker and symptom data collected during the course of disease.



In 2023, we made significant progress across our two AI-led programmes. Having analysed the unique human challenge trial data with the expertise of leading AI providers CytoReason and OneThree Biotech, our AI programmes created significant value by identifying new drug targets for influenza and new drugs for the treatment of RSV. AI-led solutions typically enable faster target identification, at lower cost, reduced risk, and potentially increased likelihood of success. We continue to actively discuss the exciting outputs from our AI-led drug discovery programmes with prospective partners.

Influenza

In June 2023, our AI-led programme with CytoReason yielded several breakthroughs. The programme identified multiple unique drug targets that hold the potential to block influenza disease progression and aid recovery by focussing on the body's response to infection and identifying the processes responsible for driving the disease. The outputs of the AI-led target discovery were evaluated by both Poolbeg and CytoReason's team of expert biologists and data scientists to identify the top-ranking genes potentially suitable for the treatment of influenza. In October 2023, our Scientific Advisory Board (SAB) endorsed the prioritisation of a select number of targets which validated our approach and strategy going forward.

Prioritisation was based on several key criteria, including the strategic opportunities available for Poolbeg to meaningfully progress the targets. The members of the SAB considered the data packages and were impressed with the outputs of the programme, and a consensus was reached on the prioritised list of novel drug targets to bring forward. They also provided valuable insight into how to most effectively validate the targets and maximise near term value in the targets. We continue to discuss the data from this programme with prospective partners.

Identification of drug targets from this unique dataset has previously been successful as p38 MAPK, inhibited by POLB 001, was identified as a driver of severe influenza but this required manual analysis that took several years and significant investment. However, through the utilisation of CytoReason's cutting-edge AI technology, Poolbeg identified multiple novel drug targets in just 15 months. Moreover, CytoReason's analysis independently confirmed the significance of the p38 MAPK pathway in severe influenza, providing further validation for Poolbeg's POLB 001 programme.

Respiratory Syncytial Virus (RSV)

We successfully identified a number of drug compounds which are novel treatment methods for RSV as part of our AI-led programme with OneThree Biotech in 2022. These compounds with existing safety and pharmacodynamic Phase 1 clinical data could, if successfully validated, be repositioned as Phase 2 ready novel treatments for RSV patients. This significant breakthrough demonstrated the power of AI in accelerating drug discovery and the identification reaffirmed our confidence in the value of our data and our technology driven programmes.

In Q4 2023, we announced the positive outputs from our lab-based analysis of these drugs in RSV infection models. Our team of scientific experts reviewed the comprehensive data package obtained from this lab-based analysis and strategically prioritised a select number of the RSV drug candidates. We are actively exploring the most effective way to progress the prioritised drug candidates in order to generate value. We believe the data obtained from this analysis is a reflection of the high potential of this AI-led programme and supports our ongoing partnering efforts.

Oral Platform

GLP-1R agonist targeting a market due to reach US$150 billion by 2031[16]

Our Oral GLP-1 receptor (GLP-1R) agonist programme is based upon a delivery system utilising Generally Regarded as Safe (GRAS) components to encapsulate API's (active pharmaceutical ingredients) for oral delivery to specific areas of the gut and into systemic circulation for the treatment of metabolic disorders, such as diabetes and obesity. The effectiveness of the technology has already been validated via the commercialisation of encapsulated oral probiotics and nutraceuticals by AnaBio Technologies, our collaborative partner.

In 2023, we engaged with a number of Key Opinion Leaders to refine the design of our GLP-1R agonist trial. We are currently working towards the commencement of our proof-of-technology clinical trial in 2024 to demonstrate successful delivery of an oral GLP-1R agonist in humans. There is currently only one oral GLP-1R agonist on the market, which has a bioavailability of approximately 1%[17], setting a very low benchmark for success for competing delivery technology platforms. Global supply of GLP-1R agonists is currently, and predicted to remain, constrained by manufacturing capacity. Any technology which can improve bioavailability in patients has the potential to significantly reduce global shortages and improve access to patients. The global GLP-1R market is projected to reach US$150 billion by 2031 in obesity and diabetes alone.

Strategic collaboration with a Nasdaq listed biopharma company

We signed a strategic collaboration with a Nasdaq listed biopharma company in October 2023 to develop an optimised oral drug to treat a metabolic condition. Under the agreement, our partner provided funding for the development of a prototype drug utilising Poolbeg's licensed oral delivery technology to improve the formulation, shelf life and effectiveness of their therapy. Poolbeg oversaw the development of a prototype product using the collaborator's Investigational Medicinal Product designed to tailor and improve specific aspects of the drug for oral delivery. The project was an endorsement of the value of the technology to drug developers seeking effective oral delivery solutions, and in Poolbeg's ability to rapidly produce novel improved products using the platform. There is potential for us to agree similar partnerships given the broad use case of this technology across all metabolic diseases.

Oral Vaccine - €2.3 million non-dilutive grant funding

The Poolbeg-led Oral Vaccine consortium (EncOVac) was awarded €2.3 million in non-dilutive grant funding and in 2023, the research plan, Consortium and Grant agreements were completed. The consortium advanced into its next phase of development as the validation of the encapsulation process commenced and the programme is progressing well. This programme represents a significant commercial opportunity as it holds the potential to tackle a broad range of infectious diseases, contributing positively to global health.

Poolbeg's part of the grant award is settled annually in arrears based on matching eligible expenditure incurred by Poolbeg over the 3-year project term. Utilising the highly skilled expertise from across the consortium, it intends to develop a Phase 1 clinical trial ready oral vaccine candidate.

The consortium includes leaders in their respective fields; AnaBio Technologies, University College Dublin (UCD), and Trinity College Dublin (TCD). By delivering oral vaccines to the gut, 'mucosal immunity' can be triggered resulting in a protective response in the areas of the body where a pathogen would be inhaled or ingested such as the nose and digestive tracts. This approach prevents infections from taking hold in the

body by counteracting them at the point of entry, both reducing transmission and preventing serious disease.

Intellectual property

Poolbeg has a worldwide licence for POLB 001 for all uses in humans. In January 2023, we applied for patent protection for POLB 001 in the treatment of Cytokine Release Syndrome (CRS) arising from cancer immunotherapy generally, and for treatment of CRS arising from CAR T therapy specifically. If granted, protection will run until January 2044; extensions of term may also be available.

Additionally, in November 2023, we applied for patent protection for dosage regimens arising from the results of our LPS trial. This is not tied to any specific indication but refers to inflammation generally in any disease indication. If granted, protection will run to November 2044; extensions of term may also be available.

Since inception, we have had a keen focus upon strengthening and broadening our IP portfolio, filing for patents in key global territories to protect our product pipeline. We have developed a strong IP portfolio with US patent protection in place covering the use of a wide range of p38 MAPK inhibitors for the treatment of symptoms of severe influenza and the use of POLB 001, and structurally related analogues, for the treatment of hypercytokinemia. We also have a European patent for the class of p38 MAPK inhibitors for use in the treatment of severe influenza. This portfolio includes two families of patent applications to protect the use of POLB 001, and indeed the use of p38 MAPK inhibitors more generally, in the treatment of severe Influenza running until at least 2037 ("Immunomodulator I") and the treatment or prevention of severe influenza or hypercytokinemia until 2038 ("Immunomodulator II"). The Immunomodulator II application also includes claims to the use of POLB 001 and other p38 MAPK inhibitors in combination with an antiviral therapy.

The Company continuously assesses its patent portfolio and is vigilant in monitoring for instances of IP infringement. It is not unusual in the pharmaceutical industry for patents to be challenged. The Immunomodulator I European patent was opposed by a third party in September 2021. Further to engaging with the opposing party, Poolbeg reached an amicable conclusion in relation to the patent dispute in September 2023 without any financial compensation between the parties. This resulted in the opposing party agreeing to withdraw its opposition to the Immunomodulator I European patent and agreeing not to challenge any of Poolbeg's Immunomodulator I or Immunomodulator II patents in the future. Following the opposition withdrawal, the European Patent Office concluded that there was no need to proceed with a previously scheduled hearing, concluding the matter.

In March 2023, we were notified that we had been granted a patent by the US Patent and Trademark Office (USPTO) for our Immunomodulator II patent application and in November 2023, our Immunomodulator II patent was granted by the Japanese Patent Office. Post year end, in March 2024, we received a Notice of Allowance from the USPTO in relation to our Immunomodulator II patent application. A Notice of Allowance is a precursor to the expected formal grant of a patent. The claims which the US Patent Office have deemed acceptable to grant cover a class of drugs (including POLB 001) for treating hypercytokinemia (cytokine storm) and for preventing hypercytokinemia in a patient after an immune response has been triggered. This encompasses cytokine storm induced in any disease indication.

We are also looking at filing patents to cover other aspects of our portfolio, in particular those generated through our AI discovery programme.

Outlook and Summary

Building on the momentum of 2023, we have made significant strides across our pipeline of assets while maintaining a robust cash position through our disciplined approach to capital allocation. Our assets target large addressable markets which are attractive areas for partnering purposes including cancer immunotherapy-induced CRS, infectious diseases, and metabolic conditions, such as obesity.

Looking ahead to the remainder of 2024 and beyond, Poolbeg Pharma is well-positioned for further growth and value creation. We have made significant strides in advancing our pipeline of innovative medicines and strengthening our corporate structure, laying a solid foundation for future growth. We are focused on near term revenue generation by maximising the value of our in-house programmes through partnering and exploring new opportunities to expand our product portfolio. With a strong pipeline of assets, an industry leading team, and a robust cash position, we are well-positioned to deliver long-term value for our shareholders while making a meaningful impact on patients' lives.

Jeremy Skillington, PhD
CEO
30 April 2024

Consolidated Statement of Comprehensive Income
For the year ended 31 December 2023

	Note	**2023 £'000**	2022 £'000
Revenue		**-**	-
Cost of sales		**-**	-
Gross profit		**-**	-
Administrative expenses		**(3,376)**	(3,060)
Other operating income		**367**	278
Research and development expenses	**2**	**(1,677)**	(2,204)
Impairment of intangible assets	**4**	**(353)**	-
Operating loss		**(5,039)**	(4,986)
Finance income		**534**	209
Loss before income tax		**(4,505)**	(4,777)
Taxation	**2**	**574**	91
Loss and total comprehensive loss for the year attributable to the equity holders of the Company		**(3,931)**	(4,686)
Loss per share:			
Loss per share - basic and diluted, attributable to ordinary equity holders of the parent	**3**	**(0.79)p**	(0.94)p

Consolidated Statement of Financial Position

As at 31 December 2023

	Note	2023 £'000	2022 £'000
Assets			
Non-current assets			
Intangible assets	4	**1,930**	2,134
Total non-current assets		**1,930**	2,134
Current assets			
Trade and other receivables	5	**1,327**	962
Cash and cash equivalents		**12,171**	16,193
Total current assets		**13,498**	17,155
Total assets		**15,428**	19,289
Equity and liabilities			
Equity attributable to owners of the parent			
Share capital		**100**	100
Share premium		**23,100**	23,100
Other reserves		**2,195**	2,145
Accumulated deficit		**(10,953)**	(7,022)
Total equity		**14,442**	18,323
Current liabilities			
Trade and other payables		**986**	966
Total current liabilities		**986**	966
Total liabilities		**986**	966
Total equity and liabilities		**15,428**	19,289

Consolidated Statement of Changes in Equity

For the year ended 31 December 2023

	Note	Share capital £'000	Share premium £'000	Share based payment reserve £'000	Merger reserve £'000	Accumulated deficit £'000	Total £'000
Balance at 31 December 2021		100	23,100	261	1,455	(2,336)	**22,580**

Loss and total comprehensive loss for the year	-	-	-	-	(4,686)	**(4,686)**
Share based payments	-	-	429	-	-	**429**
Balance at 31 December 2022	100	23,100	690	1,455	(7,022)	**18,323**
Loss and total comprehensive loss for the year	-	-	-	-	(3,931)	**(3,931)**
Share based payments	-	-	50	-	-	**50**
Balance at 31 December 2023	100	23,100	740	1,455	(10,953)	**14,442**

Consolidated Statement of Cash Flows

For the year ended 31 December 2023

	Note	**2023 £'000**	2022 £'000
Cash flows from operating activities			
Loss on ordinary activities before taxation		**(4,505)**	(4,777)
Amortisation	**4**	**26**	26
Impairment of intangible assets	**4**	**353**	-
Share based payment expense		**50**	429
Finance income		**(534)**	(209)
SME R&D tax credit		**-**	91
Movements in working capital and other adjustments:			
Change in trade and other receivables		**209**	(456)
Change in trade and other payables		**20**	528
Net cash flow used in operating activities		**(4,381)**	(4,368)
Cash flow from investing activities			
Payments for intangible assets	**4**	**(175)**	(597)
Interest received from bank		**534**	209
Net cash flow used in investing activities		**359**	(388)
Net cash flow from financing activities		**-**	-
Net change in cash and cash equivalents		**(4,022)**	(4,756)
Cash and cash equivalents at beginning of year		**16,193**	20,949
Cash and cash equivalents at end of year		**12,171**	16,193

1. General Information

Poolbeg Pharma plc ("Poolbeg" or the "Company") is a public limited company incorporated in England and Wales with company number 13279507. The Company is listed on the AIM market of the London Stock Exchange (ticker: POLB.L, ISIN: GB00BKPG7Z60) and trade on the OTCQB Venture Market ("OTCQB") in the United States under the ticker POLBF.

Poolbeg is a biopharmaceutical company committed to the development and commercialisation of innovative medicines that address critical unmet medical needs with a growing emphasis on rare and orphan diseases.

2. Basis of preparation

The Results Announcement does not constitute the Company's statutory accounts for the years ended 31 December 2023 and 31 December 2022, within the meaning of Section 435 of the Companies Act 2006 but is derived from those statutory accounts. The Company's statutory accounts for the year ended 31 December 2022 have been filed with the Registrar of Companies, and those for 31 December 2023 will be delivered following the Company's Annual General Meeting. Auditors have reported on the statutory accounts for 31 December 2023 and 31 December 2022.

Compliance with applicable law and IFRS

The consolidated Financial Statements comprise those of the Company and its subsidiaries (together the "Group"). The consolidated Financial Statements of the Group have been prepared on the going concern basis and under the historical cost convention in accordance with United Kingdom adopted International Financial Reporting Standards ("IFRS") and their interpretations issued by the International Accounting Standards Board ("IASB") that are effective or issued and adopted as at the time of preparing these Financial Statements, and in accordance with those parts of the Companies Act 2006 applicable to companies reporting under IFRS.

Consolidation

The consolidated Financial Statements comprise the Financial Statements of the Company and its subsidiaries as at and for the year to 31 December 2023. Subsidiaries are entities controlled by the Group. Where the Group has control over an investee, it is classified as a subsidiary. The Group controls an investee if all three of the following elements are present: power over an investee, exposure to variable returns from the investee, and the ability of the investor to use its power to affect those variable returns. Control is reassessed whenever facts and circumstances indicate that there may be a change in any of these elements of control. Subsidiaries are fully consolidated from the date that control commences until the date that control ceases. Accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the Group. Intergroup balances and any unrealised gains or losses or income or expenses arising from intergroup transactions are eliminated in preparing the consolidated Financial Statements.

Comparative period

The comparative period is for the year to 31 December 2022.

Presentation of Balances

The Financial Statements are presented in £ which is the functional and presentational currency of the Company. Balances in the Financial Statements are rounded to the nearest thousand (£'000) except where otherwise indicated.

Summary of significant accounting policies

Research and development expenses

The costs relating to the development of products are accounted for in accordance with IAS 38 "Intangible Assets", where they meet the criteria for capitalisation.

Development costs are capitalised as an intangible asset if all of the following criteria are met:

1. The technical feasibility of completing the asset so that it will be available for use or sale;
2. The intention to complete the asset and use or sell it;

3. The ability to use or sell the asset;
4. The asset will generate probable future economic benefits and demonstrate the existence of a market or the usefulness of the asset if it is to be used internally;
5. The availability of adequate technical, financial and other resources to complete the development and to use or sell it; and
6. The ability to measure reliably the expenditure attributable to the intangible asset.

Research costs are expensed when they are incurred.

The assessment whether development costs can be capitalised requires management to make significant judgements. Management has reviewed the facts and circumstances of each project in relation to the above criteria and in management's opinion, the criteria prescribed under IAS 38.57 "Intangible Assets" for capitalising development costs as assets have not yet been met by the Company in relation to its current product candidates which are all pre Phase II. Accordingly, all of the Company's costs related to research and development projects are recognised as expenses in the income statement in the period in which they are incurred with £1,677,000 (2022: £2,204,000) expensed in the current year. Management expects that the above criteria will be met on filing of a submission to the regulatory authority for final drug approval or potentially in advance of that on the receipt of information that strongly indicates that the development will be successful.

Acquired intangible assets
Acquired intangible assets are stated at the lower of cost less provision for amortisation and impairment or the recoverable amount. Acquired intangibles assets are amortised over their expected useful economic life on a straight line basis and are tested for impairment annually. In determining the useful economic life each acquisition is reviewed separately and consideration given to the period over which the Group expects to derive economic benefit.

It is the Company's policy not to amortise assets in development that are not ready for use.

Patents and trademarks are measured initially at purchase cost and are amortised on a straight-line basis over their life from the date that they are available for use.

Amortisation for the year has been charged to administrative expenses in the Statement of Comprehensive Income. The expected useful economic life for intangible assets subject to amortisation during the year is as follows:

- Acquired licences & data - 10 years
- Patents & Trademarks - 10-20 years

Taxes
Tax comprises current and deferred tax. Current tax is the expected tax payable on the taxable income for the period, using tax rates enacted or substantially enacted at the reporting date. Deferred tax assets or liabilities are recognised where the carrying value of an asset or liability in the Statement of Financial Position differs to its tax base, and is accounted for using the statement of financial position liability method. Recognition of deferred tax assets is restricted to those instances where it is probable that taxable profit will be available against which the difference can be utilised. From 1 April 2023 the UK main corporation tax rate is 25%, increasing from 19%. This will increase the Company's future tax charge accordingly. The unrecognised deferred tax asset as at 31 December 2023 has been calculated based on the increased rate of 25%.

Where eligible the Group applies for R&D tax credits in the jurisdictions in which it operates. Where the Group has built up a track record of R&D tax credit receipts, an estimation of the potential R&D tax credit receivable for the current year has been recognised in the Income Statement. The tax credit of £574,000 in the current year relates to (1) the receipt in 2024 of R&D tax credits (£424,000) for returns submitted for the 2022 tax year and (2) an estimation for SME R&D tax credits (£150,000) to be received relating to 2023 tax year.

3. Loss per share - basic and diluted

The Group presents basic and diluted loss per share ("LPS") data for its ordinary shares. Basic LPS is calculated by dividing the loss attributable to ordinary shareholders of the Company by the weighted average number of ordinary shares outstanding during the period. Diluted LPS is determined by adjusting the loss attributable to ordinary shareholders and the weighted average number of ordinary shares outstanding for the effects of all dilutive potential ordinary shares, which comprise warrants and share options granted by the Company.

Issued share capital - ordinary shares of 0.02p each

Share Issue Details	Number of shares	Weighted average shares
31 December 2022	**500,000,000**	**500,000,000**
31 December 2023	**500,000,000**	**500,000,000**

The calculation of loss per share is based on the following:

	2023	2022
Loss after tax attributable to equity holders of the Company (£'000)	**(3,931)**	(4,686)
Weighted average number of ordinary shares in issue	**500,000,000**	500,000,000
Fully diluted average number of ordinary shares in issue	**500,000,000**	500,000,000
Basic and diluted loss per share (pence)	**(0.79)**	(0.94)

Under IAS 33.43 "Earnings per Share", the calculation of loss per share does not assume conversion, exercise, or other issue of potential shares that would have an antidilutive effect on LPS. For the current year, the effect of options would be to reduce the loss per share and as such the basic and diluted LPS are the same. The share options and warrants outstanding as at 31 December 2023 totalled 36,829,181 (2022: 36,829,181) and are potentially dilutive.

4. Intangible Assets

Group	Acquired Licences & Data £'000	Patents & Trademarks £'000	Total £'000
Cost			
At 1 January 2022	**1,500**	**81**	**1,581**
Additions	435	162	**597**
At 31 December 2022	**1,935**	**243**	**2,178**
Additions	29	146	**175**
At 31 December 2023	**1,964**	**389**	**2,353**
Amortisation and impairment			
At 1 January 2022	**18**	**-**	**18**
Amortisation charge	25	1	**26**
At 31 December 2022	**43**	**1**	**44**
Amortisation charge	25	1	**26**
Impairment	250	103	**353**
At 31 December 2023	**318**	**105**	**423**
Net book value			
Net book value at 31 December 2023	**1,646**	**284**	**1,930**
Net book value at 31 December 2022	1,892	242	2,134

The Group reviews the carrying amounts of its intangible assets to determine whether there are any indications that those assets have suffered an impairment loss. If any such indications exist, the recoverable amount of the asset is estimated in order to determine the extent of the impairment loss. Impairment indications include events causing significant changes in any of the underlying assumptions used in the income approach utilised in valuing in process R&D. These key assumptions are: the probability of success; the discount factor; the timing of future revenue flows; market penetration and peak sales assumptions; and expenditures required to complete development. In the current year an impairment charge of £353,000 (2022: nil) was made to the Consolidated Income Statement in relation to de-prioritised R&D programmes. This is as a result of the Directors reviewing ongoing programmes and concluding that the Group should concentrate the use of its resources on certain core programmes. The impairment includes all carrying values in relation to the ViralPredict Biomarker Platform and the Vaccine Discovery Platform.

5. Trade and other receivables

	2023	2022
	£'000	£'000
Prepayments and accrued income	**669**	878
Grant receivable	**31**	-
VAT recoverable	**53**	84
R&D tax credit	**574**	-
Trade and other receivables	**1,327**	962

6. Events after the reporting period

On the 15 February 2024, Cathal Friel assumed the role of Executive Chairman at the Company. Cathal was Non-Executive Chairman prior to the role change.

On 15 February 2024, the Company announced the adoption of an Employee Performance Incentive Plan (EIP) for a number of key senior management, to align medium and long term objective with those of shareholders and to encourage retention. The EIP was designed with the support of Aon, in their role as advisors to the Remuneration Committee of the Company. Under the EIP, these team members have been awarded a total of 28,247,419 nominal cost long term incentive options ("EIP Options") over ordinary shares in the Company with vesting conditional upon the weighted-average of the mid-market closing price of the ordinary shares in the Company being 17.945 pence or above over a period of fourteen calendar days (representing a c.85% premium to the share price at close of market on February 14, 2024). The EIP Options are also subject to acceleration in certain scenarios including a change of control of the Company.

Directors of the Company were awarded EIP Options as detailed in the table below:

Director	EIP Options	Grant Date	Expiry Date
Cathal Friel	4,639,175	14/02/2024	06/02/2031
Jeremy Skillington	4,639,175	14/02/2024	06/02/2031
Ian O'Connell	4,639,175	14/02/2024	06/02/2031
	13,917,525		

Other key employees were also issued 14,329,894 EIP Options.

On 19 February 2024, the Directors of the Company purchased ordinary shares of 0.02p as follows:

Director	Number
Cathal Friel	830,000
Total	830,000

On 22 February 2024, the Directors of the Company purchased ordinary shares of 0.02p as follows:

Director	Number
Jeremy Skillington	154,764
Total	154,764

On 20 March 2024, the Company announced that it received a Notice of Allowance from the US Patent Office in relation to its Immunomodulator II patent application. A Notice of Allowance is a precursor to the expected formal grant of a patent in due course.

7. Annual Report and Annual General Meeting

The Company's Annual Report and Accounts for the year ended 31 December 2023 will be distributed to shareholders in due course together with the notice of the 2024 Annual General Meeting, and will be available on the Company's website, www.poolbegpharma.com/investors/documents/

[1] Independent research commissioned by Poolbeg
[2] Amryt Pharma Annual Report & Accounts FY22
[3] Chiesi Farmaceutica, 2023
[4] Amryt Pharma, 2017
[5] FDA
[6] European Commission
[7] European Pharmaceutical Review, May 2022
[8] Fortune Business Insights, July 2023
[9] European Pharmaceutical Review, May 2022
[10] The Economist, March 2023
[11] Grand View Research. CAR T-Cell Therapy Market Analysis 2023-2030
[12] Grand View Research. Bispecific Antibodies Market Size, Share & Trends Analysis Report
[13] Datamonitor Healthcare. Forecast: Diffuse Large B-Cell Lymphoma and Multiple Myeloma, 2023
[14] Average rate from Summary of Product Characteristics (SmPCs) for Yescarta, Tecartus, Abecma, Kymriah, Carvykti, Breyanzi, Elrexfio, Columvi, Epkinly, Tecvayli and Talvey
[15] Datamonitor Healthcare. Forecast: Diffuse Large B-Cell Lymphoma and Multiple Myeloma, 2023
[16] The Economist, March 2023
[17] EMA Product information 2020