

POOLBEG PHARMA PLC
ANNUAL REPORT 2023



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Investment Case

- Experienced executive team successfully built three public life science companies & achieved multiple exits
- Three key former Amryt Pharma leaders joined Poolbeg with a track record of establishing and scaling sales infrastructures in the US & ROW

- POLB 001 – Phase 2 ready - >\$10bn market opportunity in cancer immunotherapy-induced CRS. Treatment for severe influenza
- Oral encapsulation technology – targeting obesity with Oral GLP-1R agonist
- AI-led discovery programmes targeting influenza and RSV



- Targeting near term revenue generation from commercial stage rare and orphan products
- Focused on partnering to maximise value from in-house programmes

- Cash balance of £12.2 million (31 December 2023)
- Focused on revenue generation and cashflows

STRATEGIC REPORT: 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 million¹ prior to its ultimate sale in 2023 for US\$1.48 billion². 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 million³ 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 people⁴ while in the EU, it is characterised as a disease that affects no more than one in 2,000 people⁵. 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 market⁶. It is expected to grow from US\$170 billion in 2023 to US\$368 billion by 2030 (11.6% CAGR)⁷, with orphan drug sales due to account for 20%

¹ Amryt Pharma Annual Report & Accounts FY22

² Chiesi Farmaceutica, 2023

³ Amryt Pharma, 2017

⁴ FDA

⁵ European Commission

⁶ European Pharmaceutical Review, May 2022

⁷ Fortune Business Insights, July 2023

of all prescription drug sales by 2026⁸. 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.

POLB 001

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.

AI Programmes

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.

Oral Platforms

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 diabetes⁹ 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

29 April 2024

⁸ European Pharmaceutical Review, May 2022

⁹ The Economist, March 2023

STRATEGIC REPORT: 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.

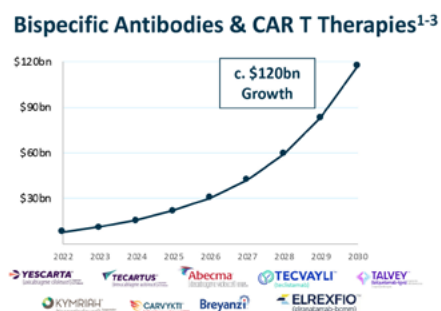
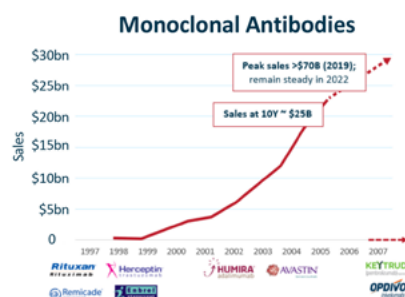
POLB 001

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^{10,11,12}.

Bispecific Antibody and CAR T Therapy market expected to show **exponential growth**, similar to antibodies in the early 2000s



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%¹³ 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 ~500,000¹⁴ 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.

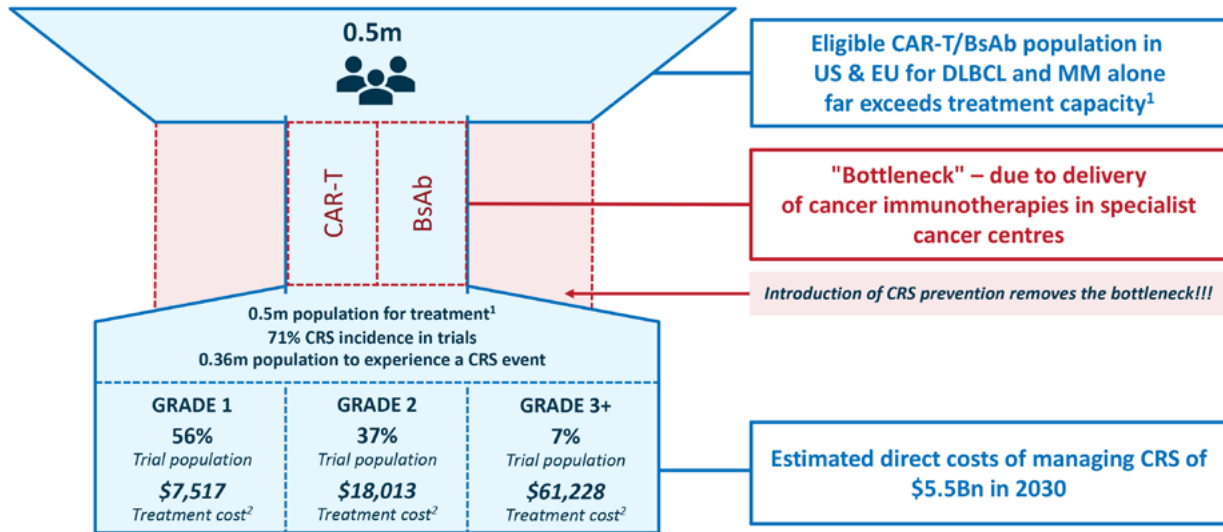
¹⁰ Grand View Research. CAR T-Cell Therapy Market Analysis 2023-2030

¹¹ Grand View Research. Bispecific Antibodies Market Size, Share & Trends Analysis Report

¹² Datamonitor Healthcare. Forecast: Diffuse Large B-Cell Lymphoma and Multiple Myeloma, 2023

¹³ Average rate from Summary of Product Characteristics (SmPCs) for Yescarta, Tecartus, Abecma, Kymriah, Carvykti, Breyanzi, Elrexfio, Columvi, Epinly, Tecvayli and Talvey

¹⁴ Datamonitor Healthcare. Forecast: Diffuse Large B-Cell Lymphoma and Multiple Myeloma, 2023



BsAb, Bispecific Antibody; CAR T, Chimeric Antigen Receptor T-cell therapy; CRS, Cytokine Release Syndrome; DLBCL, Diffuse Large B-Cell Lymphoma; MM, Multiple Myeloma
 1. Datamonitor Healthcare. Forecast: Diffuse Large B-Cell Lymphoma and Multiple Myeloma, 2023 2. Abramson JS et al. Cytokine release syndrome and neurological event costs in isocarbtagene maraleucel-treated patients in the TRANSCEND NHL 001 trial. Blood Adv. 2021 Mar 23;5(6):1695-1705.

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.



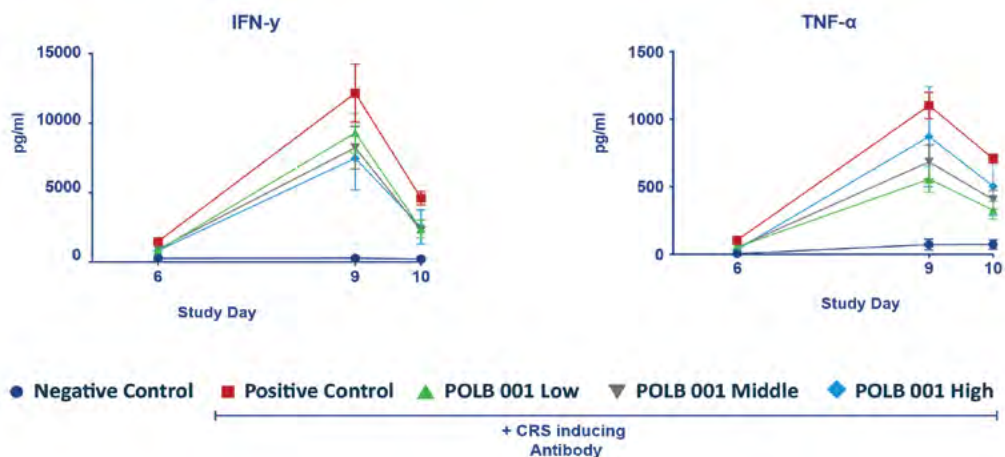
An abstract surrounding the positive LPS human challenge trial which highlighted POLB 001's potential as a groundbreaking therapy was presented at the 18th International Congress of Immunology ('IUIS'), the world's leading conference in the field of immunology

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

STRATEGIC REPORT: CEO's Operations Review continued

in cancer immunotherapy-induced CRS. The product is now Phase 2 ready and there is scientific, clinical and partner interest to advance the programme.

Positive *In Vivo* Animal Results Validate POLB 001's Potential to Address Cancer Immunotherapy-Induced CRS



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."

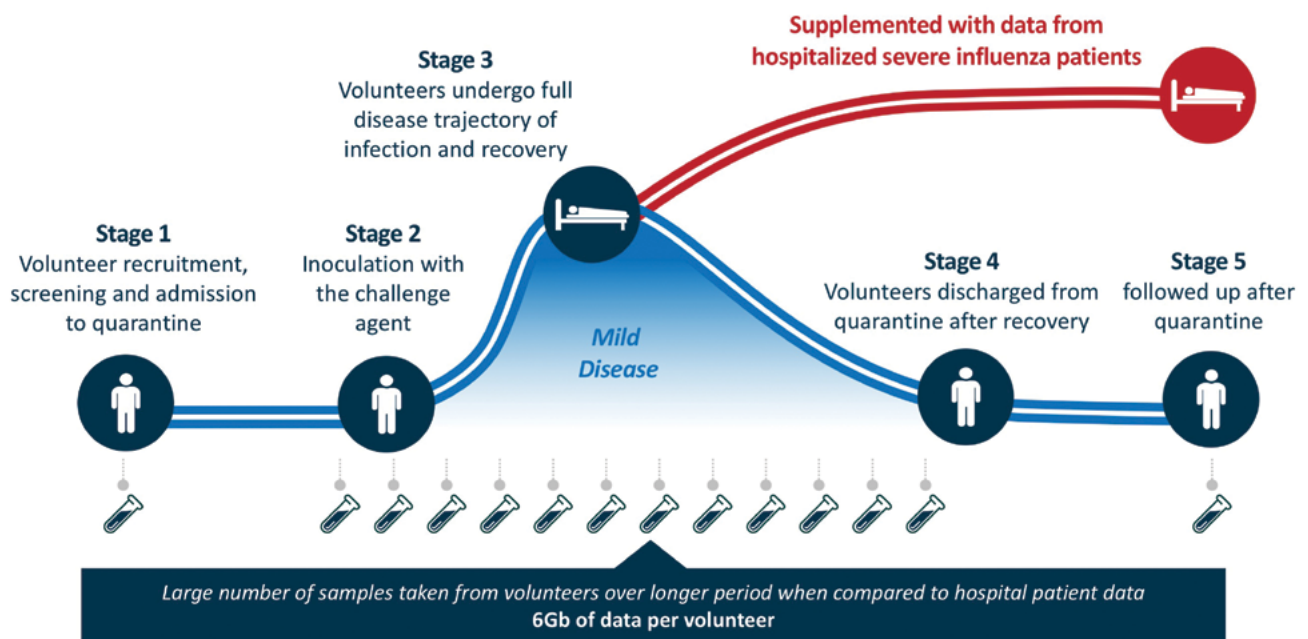
"If there was a therapy that was orally delivered, a whole lot of infrastructure requirement falls away."

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.

STRATEGIC REPORT: CEO's Operations Review continued

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 2031¹⁵

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%¹⁶, 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.

¹⁵ The Economist, March 2023

¹⁶ EMA Product information 2020

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 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

CEO

29 April 2024

STRATEGIC REPORT:

Principal Risks and Uncertainties

Poolbeg is subject to a range of risk factors relating to the business and its operations in the biotechnology/pharmaceutical industry. Poolbeg’s success is rooted in its ability to develop our clinical assets and in the future commercialise approved and marketed drugs. To effectively manage the principal operational risks affecting the Group, the Board of Directors meet regularly to review Poolbeg’s operational progress against its strategy and key objectives. In addition, the senior management team meets weekly to review the operational progress of all key projects, and to identify and discuss all key issues and risks.

The following table summarises the principal risks and uncertainties of the Group:

Risk	Details	Mitigation
Organisational Risk	<p>Poolbeg’s future success is dependent on the experience and skills of the executive Directors and senior management to successfully execute its strategy. The loss of key contributors would present a risk to the business.</p> <p>Finding and hiring any additional personnel and replacements could be a costly and time consuming process, particularly in the biotechnology/pharmaceutical industry.</p>	<p>The Board believes that the senior management team is appropriately structured for Poolbeg’s size and following the recent strengthening of the team by the addition of new senior executives is not overly dependent upon any particular individual. Poolbeg has entered into contractual arrangements with these individuals with the aim of securing the services of each of them. Staffing levels, notice periods and contingent arrangements are kept under regular review to ensure that they are appropriate to maintain business continuity. Remuneration packages and staff rewards are reviewed to encourage the long-term maintenance of staff and to align incentivisation with Company objectives.</p>
Competition Risk	<p>The biotechnology and pharmaceutical industries are very competitive. Poolbeg’s competitors include major multinational pharmaceutical companies, biotechnology companies and research institutions. Many of its competitors have substantially greater financial, technical and other resources, such as larger research and development staff. Poolbeg’s competitors may succeed in developing, acquiring or licensing drug product candidates that are earlier to market, more effective or less costly than any product candidate which Poolbeg is currently developing or which it may develop and this may have a material adverse impact on Poolbeg including on its ability to partner its programmes.</p>	<p>Poolbeg seeks to develop its products to ensure they are competitive and monitors its intellectual property rights to identify and protect against any infringements. Poolbeg’s selection criteria for products includes potential for non-dilutive funding, identifying areas of unmet medical need, market opportunity, and the ability and complexity of rapidly producing early human efficacy data including through the use of challenge studies.</p>

Risk	Details	Mitigation
Development Risk	<p>Poolbeg has a number of drug candidates in various stages of clinical and pre-clinical development. Our management team understand that a high incidence of delay or failure to produce valuable scientific results will not support Poolbeg's strategy.</p> <p>Clinical trials can be expensive, time consuming and difficult to design and implement and involve uncertain outcomes. Furthermore, results of earlier pre-clinical studies and clinical trials may not be predictive of results of future pre-clinical studies or clinical trials.</p>	<p>Poolbeg's approach of smart trial design, use of cutting edge technology, and a focus on product candidates where we can quickly produce early human efficacy data helps to mitigate this risk.</p>
Regulatory Risk	<p>The regulatory approval processes of the EMA, FDA, MHRA and other comparable regulatory agencies may be lengthy, time-consuming and the outcome is unpredictable. Poolbeg's future success is dependent upon its ability to rapidly develop and partner its product candidates.</p> <p>In addition, positive human efficacy data does not guarantee that a product will be partnered by Poolbeg.</p>	<p>The Board and management team have a broad network of industry contacts who help ensure that best industry practices are observed in all our trials and all legal compliance is up to date and in order.</p> <p>The Board reviews the partnering potential of all products Poolbeg has brought into its pipeline and is confident that with positive human efficacy, a market exists to partner its products.</p>
Intellectual Property Risk	<p>If Poolbeg is unable to obtain, maintain, defend or enforce the intellectual property rights covering its products, third parties may be able to make, dispose (or offer to dispose) of, use, import or keep products that would otherwise infringe the Group's patents and which would materially adversely affect Poolbeg's ability to compete in the market.</p> <p>Patent protection is important for Poolbeg's competitive position in its planned product lines and a failure to obtain or retain adequate protection could have a material adverse effect on Poolbeg's business, prospects, financial condition and/or results of operations.</p>	<p>To the extent possible, Poolbeg monitors competing products. Poolbeg engages external advisors to assist it in maintaining its IP portfolio, and where appropriate, to ensure that its business IP rights are safeguarded in all of the territories in which it operates. Poolbeg also looks to maintain its propriety rights when entering into contractual relationships.</p>

STRATEGIC REPORT:

Principal Risks and Uncertainties *continued*

Risk	Details	Mitigation
Funding and Partnering Risk	<p>Developing pharmaceutical products requires significant funding to bring the product to the point of monetisation. Poolbeg looks to partner early in the development process of its drug candidates. There is no guarantee that suitable partners will be secured. Poolbeg may need to raise additional funding to undertake development work and bring our products to the point of monetisation.</p> <p>There is also no certainty that it will be possible to raise any additional funds at all or on acceptable terms. Debt financing, may place restrictions on the financial operating activities of the Group and if Poolbeg is unable to obtain additional financing, it may be required to reduce the scope of its operation.</p>	<p>Poolbeg’s clinical development strategy is to demonstrate early clinical proof-of-mechanism and/or proof-of-concept thereby enabling early monetisation, through licensing or partnering.</p> <p>Poolbeg will also seek to reposition products with existing positive clinical safety data, further reducing the requirement for additional spend on clinical trials. Additionally, Poolbeg actively explore routes for non-dilutive grant funding to support the development of its pipeline.</p>
M&A Risk	<p>The Board has set strategic initiatives that include commercialising approved and marketed drugs alongside the development of the Group’s existing assets. The Group continues to evaluate and identify these opportunities. There can be no assurance that the Group will be able to conclude successfully any of the opportunities identified. Furthermore, there is no certainty that any acquisition, partnership or other opportunity completed will prove successful.</p>	<p>The Board and senior management team, have experience in successfully identifying, integrating and commercialising opportunities. The senior management team was recently supplemented with new hires to help implement the Board’s strategic initiatives. The internal team will be complemented with external experts to assist in the appraisal process.</p>
Macro-economic and Geopolitical Risk	<p>There is an ongoing risk to Poolbeg due to unexpected global events that may negatively impact its ability to operate.</p> <p>This includes any escalation of geopolitical events globally. Such events have led to high rates of inflation, exchange rate volatility, higher cybersecurity risk and supply chain disruptions and could adversely impact Poolbeg’s business, including executing of our preclinical studies and clinical trials.</p>	<p>To the extent possible, Poolbeg aims to monitor the macro-economic and political environment so as to take such actions it deems in its best interests to mitigate the impact of various shocks.</p> <p>Poolbeg continues to invest in its IT infrastructure and support systems in order to improve its security and resilience and ability to operate in the event of cyber-attacks.</p>

STRATEGIC REPORT:

Section 172 Statement

Section 172 of the Companies Act 2006 Statement

The Directors confirm that they have acted in the way they consider, in good faith, would be most likely to promote the success of the Company for the benefit of its shareholders. In doing so, the Directors, amongst other matters, have considered the following:

a) the likely consequences of any decision in the long term:

The Group's outlook is set out in the Chairman's Statement and CEO's Operations Review on pages 2 and 4. Associated risks are highlighted throughout the Strategic Report.

b) the interests of the Group's employees:

Our employees are fundamental to us achieving our long-term strategic objectives. Employee well being and development has continued to be a priority during 2023.

c) the need to foster the Group's business relations with suppliers, customers and others:

As a growing business, successful and effective engagement with customers and suppliers is paramount to meeting our strategic objectives. Senior management engages in regular meetings with key stakeholders through a variety of channels to promote the building of long term relationships.

d) the impact of the Group's actions on the community and the environment:

The Group operates honestly and transparently. We consider the impact on the environment on our day-to-day operations and how we can minimise this.

e) the Group's reputation for high standards of business conduct:

Our intention is to behave in a responsible manner, operating within the high standard of business conduct and good corporate governance, as highlighted in the Corporate Governance Statement on page 16.

f) the need to act fairly between members of the Company:

The Directors recognise that members have different view and objectives. Poolbeg engages in active communications with shareholders as detailed in the Corporate Governance Statement on page 16.

The Strategic Report on pages 4 to 13 was approved by the Board on 29 April and signed on its behalf by:

Jeremy Skillington

CEO

CORPORATE GOVERNANCE: Board of Directors



Cathal Friel, Executive Chairman

Cathal Friel is a seasoned serial entrepreneur with a long and successful history and to date has listed five companies on the London Stock Exchange. Cathal is Managing Director of Raglan Capital and serves as Chairman and co-founder of Poolbeg Pharma plc. Poolbeg was established as a spin-off from hVIVO plc in 2021, where Cathal is also co-founder and Chairman. Cathal also co-founded and sits on the Board of Directors of European Green Transition plc, which listed on the London Stock Exchange in April 2024. Cathal co-founded Amryt Pharma plc which listed on the London Stock Exchange in 2016 and dual listed on Nasdaq in 2020 and was later sold to Chiesi Farmaceutici for \$1.48bn in April 2023. Prior to that, he was co-founder and Chairman of Fastnet Oil & Gas plc, which listed on the London Stock Exchange in 2012.

Cathal began his working career a little earlier than most by having to step in to help run the family business in 1981 at the relatively young age of 16 due to a family illness. He went on to complete his education by taking night classes and received an MBA from the University of Ulster in 1990. Cathal then spent the following five years lecturing on a part-time basis on International Marketing and Business Planning at the University of Ulster whilst in tandem running his own technology services business. In 2001, Cathal was part of the team that successfully established Merrion Stockbrokers in Dublin. Following Merrion's trade sale in 2006, he founded Raglan Capital which is renowned for building in-house companies that are listed on the public stock markets. Cathal was a finalist in the international category of the EY Entrepreneur of the Year 2020.



Jeremy Skillington, Chief Executive Officer

Jeremy Skillington, PhD began his biotechnology career in the Business Development group of Genentech, Inc in California in 2002. At Genentech he was responsible for executing over 40 licensing, investment and collaboration transactions. Returning to Ireland in 2009, Jeremy led Business Development and was a member of the Senior Management team at Opsona Therapeutics Ltd before becoming a founder and CEO of immuno-oncology company TriMod Therapeutics Ltd. In 2014 Jeremy joined German life science investment fund HS Lifesciences GmbH to provide start-up and business development support to portfolio companies ImmunoQure AG and Ethris GmbH.

Jeremy joined Inflazome Ltd on its founding in 2016 and as VP of Business Development was instrumental in their acquisition by Roche in September 2020 for €380m upfront and significant downstream milestones for their portfolio of NLRP3 inflammasome inhibitors. He has been CEO of publicly listed Poolbeg Pharma Plc since June 2021.

Jeremy studied Biochemistry at the University of Galway, Ireland where he was awarded his PhD. He performed post-doctoral research at the University of California, San Francisco in the lab of Prof Rik Derynck. He is currently an Adjunct Assistant Professor at Trinity College, Dublin in the School of Biochemistry & Immunology.



Ian O'Connell, Chief Financial Officer

Ian O'Connell is an experienced financial professional with a depth of healthcare and public markets experience. In 2017 he co-founded Open Orphan plc (now named hVIVO plc), was made a Board Observer and as VP Corporate Development, he led the acquisition of hVIVO plc and the reverse takeover of Venn Life Sciences plc. As a member of the core senior management team, Ian helped drive the company to its position today as a world leader in the testing of infectious and respiratory disease products using human challenge studies.

Prior to this, Ian worked closely with Cathal Friel and Amryt's senior management on the establishment of Amryt Pharma plc. Ian gained Corporate Finance experience at both Raglan Capital and Deloitte Corporate Finance. Ian has a BSc (Hons) in Finance from University College Cork and is a Member of Chartered Accountants Ireland.



Eddie Gibson, Non-Executive Director

Eddie Gibson is a seasoned biopharma leader. Eddie has a strong commercial track record of launch and general management in both pharmaceuticals and biotechs with over 25 years' experience leading biopharma organisations with experience working across multiple geographies and senior roles within the industry. Eddie has personally led many major European launches and also led the creation and implementation of global access plans in a wide range of therapy areas including oncology, haematology, virology, neuroscience, cardiovascular disease and diabetes.

As founder of Wickenstones, a pharma market access consultancy, Eddie has led diverse teams to develop and deliver complex plans for market access and has been instrumental in the facilitation of plans to deliver new pharmaceuticals to the global market. Eddie also acts as an advisor and NED to both biotech start-ups and as an advisor to the Korean Health Development Initiative – a government advisory committee designed to accelerate the biotech and pharmaceutical industries in South Korea.



Professor Luke O'Neill, Non-Executive Director

Luke O'Neill is Professor of Biochemistry in the School of Biochemistry and Immunology, Trinity Biomedical Sciences Institute at Trinity College Dublin, Ireland. He is a world expert on innate immunity and inflammation. His main research interests include Toll-like receptors, Inflammasomes and Immunometabolism. He is listed by Thompson Reuters/ Clarivates in the top 1% of immunologists in the world, based on citations per paper. Professor O'Neill is co-founder of Sitryx, which aims to develop new medicines for inflammatory diseases. Another company he co-founded, Inflazome was acquired by Roche.

Luke was awarded the Royal Dublin Society / Irish Times Boyle Medal for scientific excellence, the Royal Irish Academy Gold Medal for Life Sciences, The Society for Leukocyte Biology (SLB) Dolph O. Adams award, the European Federation of Immunology Societies Medal and in 2018 the Milstein Award of the International Cytokine and Interferon Society. Luke is a member of the Royal Irish Academy, EMBO (European Molecular Biology Organisation) and a Fellow of the Royal Society. In 2023 he was appointed to the governing body of the European Research Council, the EU's premier funder of fundamental research with an annual budget of €2bn.



Professor Brendan Buckley, Non-Executive Director

Prof. Brendan Buckley is a medical graduate of University College Cork and a doctoral graduate of Oxford University. For most of his career he worked in academic clinical practice as a consultant physician. He holds professorial titles in the faculties of Medicine at Universities in Cork and Dublin. He has over 30 years' experience in clinical research in roles as chief investigator, chair of data and safety monitoring committees and on institutional review boards.

He became Chief Medical Officer of ICON plc, following their acquisition of Firecrest Clinical Ltd, which he had co-founded. He was a member of ICON plc's Executive Leadership Team and was actively involved in M&A targeting, assessment and diligence. Firecrest was one of a number of companies focused on clinical trial innovation which he co-founded and sold.

Brendan was a non-executive director of the Irish national medicines regulatory authority (now the Health Products Regulatory Authority) between 2004 and 2011. He was a member of the inaugural European Medicines Agency (EMA) Committee for Orphan Medicinal Products (COMP) and of the EMA Scientific Advisory Group for Diabetes and Endocrinology as well as teaching on Food and Drug Administration (FDA) advanced courses on clinical trials. He serves on the boards of various pharma development and services companies, some of which he has co-founded. Brendan has over 150 scientific publications, including the key opinion-leading book 'Re-Engineering Clinical Trials'.

CORPORATE GOVERNANCE:

Corporate Governance Statement

Compliance Statement

The Directors recognise the value and the importance of high standards of corporate governance and, given the Group's size and the constitution of the Board, have decided to apply the recommendations of the Corporate Governance Code, published by the Quoted Companies Alliance in April 2018 ("QCA Code").

The Board has established high standards of corporate governance since its inception and agrees that Poolbeg's success is enhanced by the imposition of a strong corporate governance framework. Accordingly, in recognition of the need to maintain continued best practice the Board actively monitors its composition and skills balance to ensure we uphold the ten principles outlined in the QCA Code, so far as practicable and having regard to the size and nature of the Company's business. Further details on how the Company applies the QCA Code are detailed on the Corporate Governance section of the Company's website: (<https://www.poolbegpharma.com/investors/corporate-governance/>).

Board Composition and Independence

The Board meets at least five times a year to review, formulate and approve the Group's strategy, budgets and corporate actions and oversee the Group's progress towards its goals. The Board has established an Audit Committee and a Remuneration Committee with formally delegated duties and responsibilities and with written terms of reference. From time to time, separate committees may be set up by the Board to consider specific issues when the need arises. Currently the Company does not have a nomination committee, as the Board does not consider it appropriate to establish one at this stage of the Company's development. The Board will take decisions regarding the appointment of new directors as a whole and this will follow a thorough assessment of a potential candidate's skill and suitability for the role.

The Board currently consists of the Executive Chairman, two other Executive Directors, and three Non-Executive Directors, one of whom, Eddie Gibson, acts as Senior Independent Director. The Company regards three of the Non-Executive Directors as "independent Non-Executive Director". The Board has determined that Professor Brendan Buckley, Eddie Gibson and Professor Luke O'Neill are independent in character and judgement and that there are no relationships or circumstances which could materially affect or interfere with the exercise of their independent judgement. As respected industry experts Professor Brendan Buckley and Professor Luke O'Neill are also members of the Scientific Advisory Board. They receive an annual fee of £15,000 for this role which is not considered to be material in affecting their independence.

The Board believes this combination of Executive and Non-Executive Directors allows it to exercise objectivity in decision making and proper control of the Group's business and that this composition is appropriate in view of the size and requirements of the Group's business. However, the Board will continue to monitor the composition and balance of the Board.

Audit Committee

The Audit Committee comprises Eddie Gibson as chair, replacing Patrick Ashe in the role on 30 November 2023, with Brendan Buckley, appointed on 15 February 2024, as the other member and meets at least twice a year. Eddie Gibson, the Audit Committee chair is considered to be independent and to have recent relevant financial and commercial experience including acting as country manager for large pharmaceutical companies. Cathal Friel and Patrick Ashe served as members of the Audit Committee during the year, stepping down on 15 February 2024 and 30 November 2023 respectively. The principal duties of the Audit Committee are to review the half-yearly and annual financial statements before their submission to the Board and to consider any matters raised by the auditors. The Audit Committee also reviews the independence and objectivity of the auditors.

The terms of reference of the Audit Committee reflect current best practice, including authority to:

- recommend the appointment, re-appointment and removal of the external auditors; and
- ensure the objectivity and independence of the auditors including occasions when non-audit services are provided.

The Audit Committee may seek information from any employee of the Group and obtain external professional advice at the expense of the Group if considered necessary. Due to the relatively low number of personnel employed within the Group, the nature of the business and the current control and review systems in place, the Board has decided not to establish a separate internal audit department.

Remuneration Committee

The Company has established a formal and transparent procedure for developing policy on executive remuneration and for fixing the remuneration packages of individual Directors. No Director is involved in deciding their own remuneration.

The Remuneration Committee comprises Brendan Buckley as chair, replacing Eddie Gibson in the role on 30 November 2023, with Eddie Gibson as the other member. Brendan Buckley has substantial experience as a member of Remuneration Committees of AIM quoted companies. Cathal Friel and Patrick Ashe served as members of the Remuneration Committee during the year, stepping down on 24 May 2023 and 30 November 2023 respectively. The Remuneration Committee considers the employment and performance of individual

Executive Directors and determines their terms of service and remuneration. It also has authority to grant options as part of overall remuneration packages.

Meetings and Attendance

The directors' attendance at Board and Committee meetings during the year is shown below:

Director	Board	Audit Committee	Remuneration Committee
Cathal Friel	5/5	2/2	1/1
Jeremy Skillington	5/5	–	–
Ian O'Connell	5/5	–	–
Patrick Ashe ^A	3/4	2/2	1/1
Eddie Gibson	5/5	2/2	1/1
Luke O'Neill	4/5	–	–
Brendan Buckley ^B	2/2	–	–
Total meetings held in the year	5	2	1

^A Resignation date 30 November 2023

^B Appointed 24 May 2023

Scientific Advisory Board

Poolbeg has established a Scientific Advisory Board including Professor Luke O'Neill, Dr. Elaine Sullivan, Professor Daniel F. Hoft, and Professor Brendan Buckley whose deep-rooted experience provides Poolbeg with invaluable insights and expertise in continuing to evaluate new assets and in the development of our existing product pipeline.

Internal Control and Risk Management

The Board has ultimate responsibility for risk management and the internal control procedures maintained. The procedures in place are designed to manage rather than eliminate risk of failure to achieve Company objectives and can only provide reasonable assurance against material misstatement or loss. Principal Risks and Uncertainties are discussed in the Strategic Report and financial risk management objectives and policies are outlined in note 16 of the financial statements.

Communications with Shareholders

The Board attaches great importance to communication with both institutional and private shareholders and engages in regular shareholder communication via Company RNS announcements, the Company website www.poolbegpharma.com, investor presentations, and shareholder meetings as appropriate.

The Board views the Company's annual report and accounts as well as its half year report as key communication channels through which progress in meeting the Group's objectives and updating its strategic targets can be given to Shareholders. In addition, the Board uses the Annual General Meeting ("AGM") as a primary mechanism to engage with Shareholders, both to give information and receive feedback about the Company and its progress. Details of the arrangements for the AGM and the resolutions to be proposed will be provided in a separate notice of the AGM that will be sent to Shareholders.

The Poolbeg management team undertake meetings with key Shareholders and analysts following publication of full and half year results in order to answer questions and ensure that the key messages are properly understood and effectively communicated onward.

CORPORATE GOVERNANCE: Group Directors' Report

The Directors of Poolbeg Pharma plc (the “Company”) present their report and the Financial Statements of the Company and its subsidiary undertakings (together the “Group” or “Poolbeg”) for the year ended 31 December 2023. The Company is registered in England and Wales with registered number 13279507.

Principal Activities

The principal activity of the Group is the development and commercialisation of innovative medicines that address critical unmet medical needs with a growing emphasis on rare and orphan diseases. Poolbeg has a robust development pipeline and is focused on strategically commercialising approved and marketed drugs to support the growth of the Company and the development of our pipeline of innovative products.

Review of the Year

The key performance indicators for the Group are based on the overall performance of the Group and the achievement of strategic objectives, specifically focussed on R&D programme development and the identification of suitable commercial projects to enhance the expansion of the Group.

As the Company is pre-revenue, a core focus of the business is on the progression of R&D programmes cost effectively through the clinic in order to best position the projects for partnering and future commercialisation. During 2022 and 2023 the Group managed its first clinical trial, completing the LPS human challenge trial on time and on budget. The Group also successfully advanced its AI programmes achieving key milestones in 2023 and strategically expanded POLB 001 to oncology while expanding and enhancing the overall intellectual property portfolio. During the current year the clinical trial design of the GLP-1R agonist programme was progressed as the Group works towards the commencement of the proof-of-technology clinical trial in 2024.

A summary of Poolbeg’s business activities during the year is set out in:

- The Chairman’s Statement on page 2
- The CEO’s Operations Review on page 4

These form part of the Strategic Report and include commentary on the position of the Group at year end, performance during the year and likely future developments.

Currently all of the Group’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. Details of the research and development activity during the year and planned future activity are included in the Strategic Report.

In addition, Principal Risks and Uncertainties are discussed in the Strategic Report and financial risk management objectives and policies are outlined in note 16 of the financial statements.

Results and Dividends

The results for the year are set out on pages 29 to 35 and are also discussed in the Strategic Report. The Directors do not recommend payment of a dividend.

Stakeholder Engagement

Engagement with the Company’s major stakeholders is detailed in the Corporate Governance Statement and the Company website.

Directors

Biographical details of Poolbeg’s Directors are shown on pages 14 to 15. The Directors who served on the Board during the year and to the date of this report are as follows:

Director	Capacity	Appointed Date	Resignation Date
Cathal Friel	Executive Chairman ^A		
Jeremy Skillington	Chief Executive Officer		
Ian O’Connell	Chief Financial Officer		
Patrick Ashe	Non-Executive Director		30 November 2023
Eddie Gibson	Non-Executive Director		
Luke O’Neill	Non-Executive Director		
Brendan Buckley	Non-Executive Director	24 May 2023	

^A Non-Executive Chairman up to 15 February 2024

All new directors appointed by ordinary resolution since the previous AGM are required to seek election at the next AGM and one third of the other directors (or if the number is not a multiple of three, this shall be rounded down to the nearest whole number) retire annually in rotation in accordance with the Company's articles of association. If there are only two directors subject to retirement by rotation at least one of them shall retire.

Directors' Remuneration

The remuneration of Directors for the year ended 31 December 2023 was as follows:

Director	Base Salary and Fees ^A £'000	Bonuses £'000	Pension Contributions £'000	Other Benefits £'000	Other Fees £'000	2023 Total £'000	2022 Total £'000
Cathal Friel	100	50	–	–	–	150	138
Jeremy Skillington	250	83	25	4	–	362	310
Ian O'Connell	145	73	15	4	–	237	220
Patrick Ashe ^B	32	–	–	–	–	32	35
Eddie Gibson	35	–	–	–	–	35	35
Luke O'Neill ^C	25	–	–	–	15	40	40
Brendan Buckley ^{C, D}	16	–	–	–	8	24	–
Total	603	206	40	8	23	880	778

^A Where applicable, base fees include fees received for being a chair of a Board committee – £10,000 per annum

^B Resignation date 30 November 2023

^C Other fees relate to his role on the Scientific Advisory Board - a fee of £15,000 per annum

^D Appointed 24 May 2023

Base salaries are reviewed annually, with the levels of increases for Executive Directors taking account of the performance of the Group, individual performance, additional responsibilities and external indicators such as inflation and industry comparatives. Overall long-term incentives are also reviewed annually to ensure that the Executive Directors incentives are aligned with the long-term strategic goals of the Group.

The contracts of Executive Directors may be terminated by either party giving notice to the other as set out below:

Director	Notice Period
Cathal Friel	5 months
Jeremy Skillington	6 months
Ian O'Connell	4 months

The Remuneration Committee, in discussion with the Executive Directors, review annual performance at the end of each calendar year. The Executive Chairman, CEO and CFO may be eligible for annual bonuses of up to 50% of base salary, at the Company's absolute discretion. Independent Non-Executive Directors do not participate in any discretionary bonus or Company share option scheme.

Post year end (see note 18), the Company adopted an Employee Performance Incentive Plan (EIP) for a number of key senior management, to align medium and long term objectives 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, Executive Directors have been awarded a total of 13,917,525 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 14 February 2024). The EIP Options are also subject to acceleration in certain scenarios including a change of control of the Company.

CORPORATE GOVERNANCE:

Group Directors' Report continued

Directors and their Interests

Interest in ordinary shares of 0.02p

The Directors of the Company held the following interest in the ordinary shares of Poolbeg Pharma plc:

Director	Date of this report %	Date of this report Number	31 December 2023 %	31 December 2023 Number	31 December 2022 Number
Cathal Friel	7.44	37,219,757	7.28	36,377	36,389,757
Jeremy Skillington	0.17	873,497	0.14	718,733	718,733
Ian O'Connell	1.67	8,326,839	1.67	8,326,839	8,326,839
Patrick Ashe	N/A	N/A	N/A	N/A	263,147
Eddie Gibson	–	–	–	–	–
Luke O'Neill	–	–	–	–	–
Brendan Buckley	0.53	2,631,474	0.53	2,631,474	N/A

Share options and warrants

The Directors of the Company held the following share option and warrants of Poolbeg Pharma plc:

Director	Type	At 31 December 2022 & 2023		Exercise price	Grant Date	Expiry Date
		Number	Number			
Cathal Friel	Warrants	240,681		£0.10	13/07/2021	18/07/2026
Cathal Friel ^A	Share Options	3,500,000		£0.10	13/07/2021	12/07/2031
Cathal Friel ^B	Share Options	3,500,000		£0.15	13/07/2021	12/07/2031
Cathal Friel ^C	Share Options	3,500,000		£0.15	13/07/2021	12/07/2031
Jeremy Skillington ^A	Share Options	5,000,000		£0.10	13/07/2021	12/07/2031
Jeremy Skillington ^B	Share Options	5,000,000		£0.15	13/07/2021	12/07/2031
Jeremy Skillington ^C	Share Options	5,000,000		£0.15	13/07/2021	12/07/2031
Ian O'Connell ^A	Share Options	3,500,000		£0.10	13/07/2021	12/07/2031
Ian O'Connell ^B	Share Options	3,500,000		£0.15	13/07/2021	12/07/2031
Ian O'Connell ^C	Share Options	3,500,000		£0.15	13/07/2021	12/07/2031
		36,240,681				

^A The closing share price must be at least £0.10 for five consecutive business days when exercised

^B The closing share price must be at least £0.15 for five consecutive business days when exercised

^C The closing share price must be at least £0.20 for five consecutive business days when exercised

On 15 February 2024, the Directors of the Company were awarded nominal cost share options over ordinary shares in Poolbeg Pharma plc with vesting conditional upon the weighted-average of the mid-market closing price of the ordinary shares of Poolbeg Pharma plc 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).

Directors of the Company were awarded the following share options:

Director	Share 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		

Share Capital Structure

The Company's ordinary shares of 0.02p are listed on the Alternative Investment Market ("AIM") market of the London Stock Exchange (ticker: POLB.L, ISIN: GB00BKPG7Z60). At the date of this report, 500,000,000 ordinary shares of 0.02p each were in issue. Details of share issues and changes to the capital structure during the year are set out in note 12.

In March 2022, the Company's ordinary shares were approved to trade on the OTCQB Venture Market ("OTCQB") in the United States under the ticker POLBF. Poolbeg shares are available to US investors during US working hours and are priced in US Dollars. The ability to trade in the Company's ordinary shares on AIM is not affected by the OTCQB facility. As a Foreign Private Issuer the Company will have no additional reporting obligations.

Substantial Shareholdings

The Company is aware that the following had an interest of 3% or more in the issued ordinary share capital of the Company ^A:

Rank	Investor	31 March 2024 ^B	31 March 2024 ^B	31 December 2023	31 December 2023
		Number	%	Number	%
1	Cathal Friel	37,219,757	7.44	36,389,757	7.28
2	Michael Kelly	23,988,955	4.80	18,168,127	3.63

^A Except those exempt under DTR 5.1.5 regulation

^B Latest date for which information was available prior to signing the financial statements

Qualifying Indemnity Provision

The Group has in place insurance protection, including a Directors and Officers liability policy, to cover the risk of loss when management deems it appropriate and cost effective; however, in some cases risks cannot be effectively covered by insurance and the cover in place may not be sufficient to cover the extent of potential liabilities.

Going Concern

The conflict in eastern Europe, accompanied by rising inflation, interest rates and a broad degree of macro-economic and political disruption continue to create challenges for the global economy. The Group itself is well capitalised and debt-free, meaning it is able to benefit from rising interest rates on its cash reserves without any exposure to increased costs of debt. The Company does not foresee any significant problems in relation to its operations in the coming year.

After making appropriate enquiries, the Directors consider that the Company and the Group has adequate resources to continue in business for the foreseeable future. Accordingly, they continue to adopt the going concern basis in preparing the Financial Statements. As part of their enquiries the Directors reviewed budgets, projected cash flows, and other relevant information for 12 months from the date of approval of the Consolidated Financial Statements for the year ended 31 December 2023.

The Board's strategy on product development is to develop products faster and more cost effectively than the conventional biotech model and to move to partner with larger pharmaceutical and biotechnology companies. The Group focuses on development and commercialisation of innovative medicines targeting diseases with a high unmet medical need, with a growing emphasis on rare and orphan diseases. This model focusses upon developing the Group's clinical assets and commercialising approved and marketed drugs to support the growth of the Company and the development of its pipeline of products. The Group's forecasts and projections reflect the Directors' plans for the coming year and include spend in relation to progressing POLB 001 along the clinical pathway for cancer immunotherapy-induced Cytokine Release Syndrome (CRS) therapy, completion of a proof of technology clinical trial to determine that a GLP-1 agonist can be safely delivered orally in humans, ongoing research spend in relation to the Group's AI data powered drug programmes following the achievement of important milestones on the programmes in 2023 and additional spend on the asset pipeline including IP maintenance and expansion. The Group performs sensitivity analysis on its projected cashflows and when performing these sensitivities it takes into account reasonable changes in market conditions.

The Group's forecasts, taking into account reasonably possible changes as described above, show that the Group will be able to operate and have significant financial headroom for the 12 months from the date of approval of the Consolidated Financial Statements for the year ended 31 December 2023.

Political Donations

The Group made no political donations during the year.

CORPORATE GOVERNANCE:

Group Directors' Report continued

ESG Responsibility

The Board of Poolbeg recognises the importance of environmental, social and governance matters and aims to consider the differing interests of the Group's stakeholders, including its investors, employees, suppliers and business partners, when operating its business.

Events after the Reporting Period

Events after the reporting period are set out in note 18 to the Financial Statements. Likely future developments in the business are discussed in the Strategic Report.

Auditors

The Board are recommending Gravita Audit Limited for re-appointment as auditor of the Company. Gravita Audit Limited have expressed their willingness to accept this appointment and a resolution re-appointing them will be submitted to the forthcoming Annual General Meeting.

Disclosure of Information to the Auditors

The Directors confirm that: (a) they have taken all the steps that they ought to have taken to make themselves aware of any information needed by the Company's auditors for the purposes of their audit and to establish that the auditors are aware of that information and (b) so far as they are aware there is no relevant audit information of which the auditors are unaware.

Directors' Responsibilities

The Directors are responsible for preparing the Strategic Report, the Group Directors' Report and the Financial Statements in accordance with applicable law and regulations.

Company law requires the Directors to prepare Financial Statements for each financial year. Under that law the Directors have elected to prepare the Group and Company Financial Statements in accordance with International Financial Reporting Standards ("IFRSs") as adopted by the United Kingdom in conformity with the requirements of the Companies Act 2006. Under company law the Directors must not approve the Financial Statements unless they are satisfied that they give a true and fair view of the state of affairs of the Group and Company and of the profit or loss of the Group for that period. The Directors are also required to prepare Financial Statements in accordance with the Rules of the London Stock Exchange for companies trading securities on the Alternative Investment Market.

In preparing these Financial Statements, the Directors are required to:

- select suitable accounting policies and then apply them consistently;
- make judgements and accounting estimates that are reasonable and prudent;
- state whether they have been prepared in accordance with applicable IFRSs, subject to any material departures disclosed and explained in the Financial Statements;
- prepare the Financial Statements on the going concern basis unless it is inappropriate to presume that the company will continue in business.

The Directors are responsible for keeping adequate accounting records that are sufficient to show and explain the Company's transactions and disclose with reasonable accuracy at any time the financial position of the Company and enable them to ensure that the Financial Statements comply with the requirements of the Companies Act 2006. They are also responsible for safeguarding the assets of the Company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

Website Publication

The Directors are responsible for ensuring the Annual Report and the Financial Statements are made available on a website. Financial Statements are published on the Company's website in accordance with legislation in the United Kingdom governing the preparation and dissemination of Financial Statements, which may vary from legislation in other jurisdictions. The maintenance and integrity of the Company's website is the responsibility of the Directors. The Directors' responsibility also extends to the on-going integrity of the Financial Statements contained therein.

This report was approved by the Board on 29 April 2024 and signed on its behalf by:

Cathal Friel
Executive Chairman

Independent Auditor's Report

For the year ended 31 December 2023

INDEPENDENT AUDITOR'S REPORT TO THE MEMBERS OF POOLBEG PHARMA PLC

Opinion

We have audited the financial statements of Poolbeg Pharma Plc (the "Parent Company") and its subsidiaries (the "Group") for the year ended 31 December 2023 which comprise the consolidated statement of comprehensive income, the consolidated statement of financial position, the consolidated statement of cash flows, the consolidated statement of changes in equity, the company statement of financial position, the company statement of cash flows and the company statement of changes in equity and notes to the financial statements, including a summary of significant accounting policies.

The financial reporting framework that has been applied in the preparation of the Group financial statements is applicable law and UK adopted international accounting standards. The financial reporting framework that has been applied in the preparation of the Parent Company financial statements is applicable law and UK adopted international accounting standards as applied in accordance with the Companies Act 2006.

In our opinion:

- the financial statements give a true and fair view of the state of the Group's and of the Parent Company's affairs as at 31 December 2023 and of the Group's loss for the year then ended;
- the Group financial statements have been properly prepared in accordance with UK adopted international accounting standards;
- the Parent Company financial statements have been properly prepared in accordance with UK adopted international accounting standards, as applied in accordance with the Companies Act 2006;
- the financial statements have been prepared in accordance with the requirements of the Companies Act 2006.

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (UK) (ISAs (UK)) and applicable law. Our responsibilities under those standards are further described in the Auditor's responsibilities for the audit of the financial statements section of our report. We are independent of the Company in accordance with the ethical requirements that are relevant to our audit of the financial statements in the UK, including the FRC's Ethical Standard, and we have fulfilled our other ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Conclusions relating to going concern

In auditing the financial statements, we have concluded that the director's use of the going concern basis of accounting in the preparation of the financial statements is appropriate. Our evaluation of the directors' assessment of the Group and the Parent Company's ability to continue to adopt the going concern basis of accounting included reviews of expected cash flows for a period of 12 months, to determine expected cash outflow, which was compared to the liquid assets held in the Group.

Based on the work we have performed, we have not identified any material uncertainties relating to events or conditions that, individually or collectively, may cast significant doubt on the Group and the Parent Company's ability to continue as a going concern for a period of at least twelve months from when the financial statements are authorised for issue.

Our responsibilities and the responsibilities of the directors with respect to going concern are described in the relevant sections of this report.

Independent Auditor's Report continued

Key audit matters

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the financial statements of the current period and include the most significant assessed risks of material misstatement (whether or not due to fraud) we identified, including those which had the greatest effect on: the overall audit strategy, the allocation of resources in the audit; and directing the efforts of the engagement team. These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters. This is not a complete list of all risks identified by our audit.

Key audit matter	How our audit addressed the key audit matter
<p>Intangible assets</p> <p>The carrying value of the Group's intellectual property assets, at cost, as at 31 December 2023 amounted to £1,930,000 (2022: £2,134,000). The additions this year were £175,000 (2022: £597,000). Intangible assets amounting to £353,000 (2022: Nil) were impaired during the year.</p> <p>Costs amortised during the year relate to trademarks and data sets acquired and intellectual property from hVIVO, which have a fixed lifespan. The useful economic life of all the other intangibles start once they are available for use, and their amortisation will start from that point.</p> <p>The Directors have assessed whether the costs meet the criteria for capitalisation and whether there are any indicators of impairment.</p> <p>The risk is that the costs may not qualify for capitalisation or technological advancements may render the market value of the capitalised costs below its carrying value.</p> <p>Profit after tax, which is considered by management to be a key metric, is directly impacted by the amount of costs capitalised.</p>	<p>We have performed the following audit procedures:</p> <ul style="list-style-type: none"> considered whether the nature of the costs met the necessary criteria under IAS 38 for the costs to be allowed for capitalisation; vouched a sample of the additions capitalised to invoices, to confirm that they are correct capital items and have been accurately recorded; considered whether the Directors' policy for the treatment of such costs was reasonable and assessed whether the costs included in the reconciliation were in line with the Directors' policy; confirmed the Directors' assessment that the amortisation policy is reasonable; and reviewed the intangibles for any indication of impairment. <p>Based on the audit work performed we are satisfied, that although there are inherent uncertainties associated with the forecast and estimation of useful economic life of intangible assets, the directors have made reasonable assumptions about the valuation and useful economic life of intangible assets, based on past experience and expected future revenues. We are also satisfied that all necessary disclosures have been made in the financial statements.</p>
<p>Carrying value of investments in subsidiaries and recoverability of intercompany loans – parent company financial statements only.</p> <p>The Company had investments of £2,219,000 (2022: £2,169,000) at the year ended 31 December 2023.</p> <p>The Directors have confirmed all investments, including additions were correctly calculated and being held at cost.</p> <p>The amounts due from subsidiaries amounts to £10,184,000. (2022: £5,937,000).</p> <p>We identified a risk that the investment held within the parent company financial statements in its subsidiaries and amounts receivable, may be impaired.</p> <p>Management's assessment of the recoverable amount of investments in subsidiaries requires estimation and judgement around assumptions used, including the cash flows to be generated from continuing operations. Changes to assumptions could lead to material changes in the estimated recoverable amount, impacting the value of investment in the subsidiary and impairment charges.</p>	<p>We have performed the following audit procedures:</p> <ul style="list-style-type: none"> Reviewed management's assessment of future operating cashflows and indicators of impairment; Assessed the methodology used by management to estimate the future profitability of its subsidiaries and recoverable value of the investment, in conjunction with any intra-group balances, to ensure that the method used is appropriate; Assessed the reasonableness of the key assumptions used in management's estimates of recoverable value, in line with economic and industry statistics relevant to the business; Assessed the appropriateness and applicability of the discount rate applied to the current business performance; Confirmed that any adverse change in key assumptions would not materially increase the impairment loss; and Ensured that disclosures of the key judgements and assumptions, and sensitivities of the impairment loss recognised was appropriately disclosed. <p>Based on the audit work performed, we are satisfied with management's assertion that no impairment exists.</p>

Our application of materiality

The scope of our audit was influenced by our application of materiality. We set certain quantitative thresholds for materiality. These, together with qualitative considerations, helped us to determine the scope of our audit and the nature, timing and extent of our audit procedures on the individual financial statement line items and disclosures and in evaluating the effect of misstatements, both individually and in aggregate on the financial statements as a whole.

Based on our professional judgment, we determined materiality for the financial statements as a whole as follows:

	Group Financial statements	Company Financial Statements
Overall materiality	£197,000 (2022: £220,000)	£10,000 (2022: £42,000)
How we determined it	Based on 5% of net loss	Based on 5% of net loss
Rationale for benchmark applied	We believe that net loss is the primary measure used by the shareholders in assessing the performance of the Company as revenue is yet to be generated, and so costs reduction is significant to the shareholders.	We believe that net loss is the primary measure used by the shareholders in assessing the performance of the Company as revenue is yet to be generated, and so costs reduction is significant to the shareholders.
Performance materiality	£137,900 (2022: £165,000)	£7,000 (2022: £24,000)

For each component in the scope of our Group audit, we allocated a materiality that is less than our overall Group materiality. The range of materiality allocated across components was between £10,000 and £78,000.

We set performance materiality at a level lower than materiality to reduce the probability that, in aggregate, uncorrected and undetected misstatements exceed the materiality for the financial statements as a whole. Performance materiality has been set at 70% of overall materiality. We determined performance materiality with reference to factors such as our understanding of the Group and its complexity, the quality of the control environment and ability to rely on controls and the low level of uncorrected misstatements in the prior year audit.

We agreed with the Audit Committee that we would report to them misstatements identified during our audit for the Group above £9,150 (2022: £11,000) and for the Company above £1,900 (2022: £2,100) as well as misstatements below those amounts that, in our view, warranted reporting for qualitative reasons.

An overview of the scope of our audit

As part of designing our audit, we determined materiality and assessed the risks of material misstatement in the financial statements. In particular, we looked at where the Directors made subjective judgments, for example in respect of significant accounting estimates that involved making assumptions and considering future events that are inherently uncertain. As in all of our audits we also addressed the risk of management override of internal controls, including evaluating whether there was evidence of bias by the Directors that represented a risk of material misstatement due to fraud.

How we tailored the audit scope

We tailored the scope of our audit to ensure that we performed enough work to be able to give an opinion on the financial statements as a whole, taking into account the structure of the Group and the Company, the accounting processes and controls, and the industry in which they operate.

The Group financial statements are a consolidation of 4 reporting units (2022: 4 reporting units), comprising the Group's operating businesses and holding companies.

We performed audits of the complete financial information of Poolbeg Pharma Plc and Poolbeg Pharma (UK) Limited (formerly known as ORPH Pharma IP Company Limited) reporting units, which were individually financially significant. One additional reporting unit, Poolbeg Pharma (Ireland) Limited, was also individually financially significant and was audited by local component auditors in the Republic of Ireland. The sum of these significant entities accounted for 100% of the Group's absolute loss before tax (i.e. the sum of the numerical values without regard to whether they were profits or losses for the relevant reporting units) and 100% of the Group's assets and liabilities. We also performed specified audit procedures over certain account balances and transaction classes that we regarded as material to the Group at the 2 UK resident reporting units and the Irish resident reporting unit.

The fourth reporting unit, OP Holdco 2021 Limited, is a dormant entity which was acquired on 30 May 2022. Except for OP Holdco 2021 Limited, we have audited all UK resident components within the Group and performed review of the work carried out by the local component auditors, and no unaudited components remain.

Independent Auditor's Report continued

Other information

The Directors are responsible for the other information. The other information comprises the information included in the annual report, other than the financial statements and our auditor's report thereon. Our opinion on the financial statements does not cover the other information and, except to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated. If we identify such material inconsistencies or apparent material misstatements, we are required to determine whether there is a material misstatement in the financial statements or a material misstatement of the other information. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Opinions on other matters prescribed by the Companies Act 2006

In our opinion, based on the work undertaken in the course of the audit:

- the information given in the strategic report and the Directors' report for the financial year for which the financial statements are prepared is consistent with the financial statements; and
- the strategic report and the Directors' report have been prepared in accordance with applicable legal requirements.

Matters on which we are required to report by exception

In the light of the knowledge and understanding of the Company and its environment obtained in the course of the audit, we have not identified material misstatements in the Strategic report nor the Directors' report.

We have nothing to report in respect of the following matters in relation to which the Companies Act 2006 requires us to report to you if, in our opinion:

- adequate accounting records have not been kept by the Company, or returns adequate for our audit have not been received from branches not visited by us; or
- the financial statements are not in agreement with the accounting records and returns; or
- certain disclosures of Directors' remuneration specified by law are not made; or
- we have not received all the information and explanations we require for our audit.

Responsibilities of Directors

As explained more fully in the Directors' responsibilities statement set out on page 22, the Directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view, and for such internal control as the Directors determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the Directors are responsible for assessing the Group's and the Parent Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the Directors either intend to liquidate the Group or the Parent Company or to cease operations, or have no realistic alternative but to do so.

Auditor's responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance about whether the financial statements, as a whole, are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (UK) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

Irregularities, including fraud, are instances of non-compliance with laws and regulations. We design procedures in line with our responsibilities, outlined above, to detect material misstatements in respect of irregularities, including fraud. The extent to which our procedures are capable of detecting irregularities, including fraud, is detailed below.

Explanation as to what extent the audit was considered capable of detecting irregularities, including fraud

The objectives of our audit, in respect to fraud are: to identify and assess the risks of material misstatement of the financial statements due to fraud; to obtain sufficient appropriate audit evidence regarding the assessed risks of material misstatements due to fraud, through designing and implementing appropriate responses; and to respond appropriately to fraud or suspected fraud identified during the audit. However, the primary responsibility for the prevention and detection of fraud rests with both those charged with governance of the entity and management.

Our approach to identifying and assessing the risks of material misstatement in respect of irregularities, including fraud and non-compliance with laws and regulations, was as follows:

- the senior statutory auditor ensured the engagement team collectively had the appropriate competence, capabilities and skills to identify or recognise non-compliance with applicable laws and regulations;
- we identified the laws and regulations applicable to the company through discussions with Directors and other management, and from our knowledge and experience of the entity's activities.
- we focused on specific laws and regulations which we considered may have a direct material effect on the financial statements or the operations of the company, including Companies Act 2006, taxation legislation, data protection, employment and health and safety legislation.
- we assessed the extent of compliance with the laws and regulations identified above through making enquiries of management and reviewing legal expenditure; and
- identified laws and regulations were communicated within the audit team regularly and the team remained alert to instances of non-compliance throughout the audit.

We assessed the susceptibility of the Group and the Parent Company's financial statements to material misstatement, including obtaining an understanding of how fraud might occur, by:

- making enquiries of management as to where they considered there was susceptibility to fraud, their knowledge of actual, suspected and alleged fraud; and
- considering the internal controls in place to mitigate risks of fraud and non-compliance with laws and regulations.

To address the risk of fraud through management bias and override of controls, we:

- performed analytical procedures to identify any unusual or unexpected relationships;
- tested journal entries to identify unusual transactions;
- assessed whether judgements and assumptions made in determining the accounting estimates were indicative of potential bias; and
- investigated the rationale behind significant or unusual transactions.

In response to the risk of irregularities and non-compliance with laws and regulations, we designed procedures which included, but were not limited to:

- agreeing financial statement disclosures to underlying supporting documentation;
- reading the minutes of meetings of those charged with governance; and
- enquiring of management as to actual and potential litigation and claims

There are inherent limitations in our audit procedures described above. The more removed that laws and regulations are from financial transactions, the less likely it is that we would become aware of non-compliance. Auditing standards also limit the audit procedures required to identify non-compliance with laws and regulations to enquiry of the Directors and other management and the inspection of regulatory and legal correspondence, if any.

Material misstatements that arise due to fraud can be harder to detect than those that arise from error as they may involve deliberate concealment or collusion.

A further description of our responsibilities for the audit of the financial statements is located on the Financial Reporting Council's website at: www.frc.org.uk/auditorsresponsibilities.

This description forms part of our auditor's report.

Independent Auditor's Report continued

Use of this report

This report is made solely to the Parent Company's members, as a body, in accordance with Chapter 3 of Part 16 of the Companies Act 2006. Our audit work has been undertaken so that we might state to the Parent Company's members those matters we are required to state to them in an auditor's report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the Parent Company and the Parent Company's members as a body, for our audit work, for this report, or for the opinions we have formed.

Sachin Ramaiya

(Senior Statutory Auditor)

For and on behalf of
Gravita Audit Limited, Statutory Auditor
Finsgate
5-7 Cranwood Street
London EC1V 9EE
29 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	3	367	278
Research and development expenses		(1,677)	(2,204)
Impairment of intangible assets	8	(353)	–
Operating loss	4	(5,039)	(4,986)
Finance income		534	209
Loss before income tax		(4,505)	(4,777)
Taxation	6	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	7	(0.79)p	(0.94)p

The loss for the year arises from continuing operations.

There were no other items of comprehensive income for the year and therefore the loss for the year is also the total comprehensive loss for the year.

Consolidated Statement of Financial Position

As at 31 December 2023

	Note	2023 £'000	2022 £'000
Assets			
Non-current assets			
Intangible assets	8	1,930	2,134
Total non-current assets		1,930	2,134
Current assets			
Trade and other receivables	10	1,327	962
Cash and cash equivalents	11	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	12	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	14	986	966
Total current liabilities		986	966
Total liabilities		986	966
Total equity and liabilities		15,428	19,289

The Financial Statements set out on pages 29 to 50 were approved and authorised for issue by the Directors on 29 April 2024.

They are signed on the Board's behalf by:

Ian O'Connell
Chief Financial Officer

Company Number
13279507

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	13	–	–	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	13	–	–	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	8	26	26
Impairment of intangible assets	8	353	–
Share based payment expense	13	50	429
Finance income		(534)	(209)
SME R&D tax credit	6	–	91
Movements in working capital and other adjustments:			
Change in trade and other receivables	10	209	(456)
Change in trade and other payables	14	20	528
Net cash flow used in operating activities		(4,381)	(4,368)
Cash flow from investing activities			
Payments for intangible assets	8	(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	11	12,171	16,193

Company Statement of Financial Position

As at 31 December 2023

	Notes	2023 £'000	2022 £'000
Assets			
Non-current assets			
Investment in subsidiaries	9	2,219	2,169
Loans to subsidiaries	9	10,184	5,937
Total non-current assets		12,403	8,106
Current assets			
Trade and other receivables	10	254	301
Cash and cash equivalents	11	11,548	15,753
Total current assets		11,802	16,054
Total assets		24,205	24,160
Equity and liabilities			
Equity attributable to owners of the company			
Share capital	12	100	100
Share premium		23,100	23,100
Other reserves		2,195	2,145
Accumulated deficit		(1,533)	(1,341)
Total equity		23,862	24,004
Current liabilities			
Trade and other payables	14	343	156
Total current liabilities		343	156
Total liabilities		343	156
Total equity and liabilities		24,205	24,160

As permitted by Section 408 of the Companies Act 2006, no separate income statement is presented in respect of the parent company. The parent company's loss for the year was £192,000 (2022: £636,000).

The Financial Statements set out on pages 29 to 50 were approved and authorised for issue by the Directors on 29 April 2024.

They are signed on the Board's behalf by:

Ian O'Connell
Chief Financial Officer

Company Number
13279507

Company 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	(705)	24,211
Loss and total comprehensive loss for the year		–	–	–	–	(636)	(636)
Share based payments	13	–	–	429	–	–	429
Balance at 31 December 2022		100	23,100	690	1,455	(1,341)	24,004
Loss and total comprehensive loss for the year		–	–	–	–	(192)	(192)
Share based payments	13	–	–	50	–	–	50
Balance at 31 December 2023		100	23,100	740	1,455	(1,533)	23,862

Company Statement of Cash Flows

For the year ended 31 December 2023

	Notes	2023 £'000	2022 £'000
Cash flows from operating activities			
Loss for the year – continuing operations		(192)	(636)
Loss for the year		(192)	(636)
Finance income		(1,202)	(432)
Movements in working capital and other adjustments:			
Change in trade and other receivables	10	47	(20)
Change in trade and other payables	14	187	52
Net cash flow used in operating activities		(1,160)	(1,036)
Cash flow from investing activities			
Funds advanced to subsidiary companies		(3,578)	(4,194)
Interest received from bank		533	209
Net cash flow used in investing activities		(3,045)	(3,985)
Net cash flow from financing activities			
		–	–
Net change in cash and cash equivalents		(4,205)	(5,021)
Cash and cash equivalents at beginning of year		15,753	20,774
Cash and cash equivalents at end of year	11	11,548	15,753

Notes to the Financial Statements

1 General information

Poolbeg Pharma plc (“Poolbeg” or the “Company”) is a public limited company incorporated in England and Wales with company number 13279507. Details of the registered office, the officers and advisers to the Company are presented on the Company Information page at the end of this report. 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 Accounting policies

Basis of preparation

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 and the individual Financial Statements of the Company 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.

Going concern

Management believe that it is appropriate to prepare these consolidated financial statements on the going concern basis. In making that assessment, management are required to consider whether the Group can continue in operational existence for the foreseeable future, being a period of not less than twelve months from the date of the approval of the consolidated financial statements. In reaching the going concern conclusion, the cash and cash equivalents of £12.2m as at 31 December 2023 and Group’s forecasts and projections over the 24 months from year end, along with sensitivity analysis performed on the projected cashflows taking into account reasonable changes in market conditions, were considered. The Group, therefore, continues to adopt the going concern basis in preparing the consolidated financial statements. Further information is provided on page 21 of the Group Directors’ Report.

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.

The following table discloses the major exchange rates of those currencies utilised by the Group:

Foreign currency units to 1 £	€	US\$
Average year to 31 December 2023	1.1915	1.2467
At 31 December 2023	1.1534	1.2731

(€ = Euro; US\$ = US Dollars)

Foreign currency units to 1 £	€	US\$
Average year to 31 December 2022	1.1702	1.2101
At 31 December 2022	1.1284	1.2329

(€ = Euro; US\$ = US Dollars)

Accounting policies and disclosures

The accounting policies adopted are consistent throughout the financial period. Standards and amendments to IFRS effective as of 1 January 2023 have been applied by the Group.

Standards issued but not yet effective

There were a number of standards and interpretations which were in issue at 31 December 2023 but were not effective at 31 December 2023 and have not been adopted for these Financial Statements. These include:

- Amendments to IFRS 7 Financial Instruments: Disclosures – amendments regarding supplier finance arrangements (applicable on or after 1 January 2024)
- Amendments to IFRS 16 Leases – requirements on accounting for sale and leaseback after the date of transaction (applicable on or after 1 January 2024)
- Amendments to IAS 1 Presentation of Financial Statements – amendments regarding the classification of debt with covenants (applicable on or after 1 January 2024)
- Amendments to IAS 7 Statement of Cash Flows – amendments regarding supplier finance arrangements (applicable on or after 1 January 2024)

The Directors have assessed the impact of these accounting changes on the Group. To the extent that they may be applicable, the Directors have concluded that none of these pronouncements will cause material adjustments to the Group's Financial Statements.

Critical accounting judgements and key sources of estimation uncertainty

The preparation of Financial Statements in conformity with IFRS requires management to make estimates and judgements that affect the reported amounts of assets and liabilities as well as the disclosure of contingent assets and liabilities at the period end and the reported amounts of revenues and expenses during the reporting period. Estimates and judgements are continually evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances.

The Group's accounting policy descriptions set out the areas that involve significant estimation, uncertainty and critical judgement. The most significant of which are:

(a) Impairment of Intangible Assets and Investments in and Loans to Subsidiaries

The Group tests annually whether intangibles have suffered any impairment, in accordance with the accounting policy stated in note 2. The valuation uses an income approach, discounted cash flows, for valuing the carrying value of intangible assets based on assumptions within the forecast based on market inputs. Sensitivities have been applied regarding likelihood of the drug reaching the next development milestone. These calculations require the use of estimates as set out in note 8. The Group tests annually whether there is any indication that Intangible Assets have been impaired. In addition, the Group has also considered the impairment of Investments in and Loans to Subsidiaries as set out in notes 2 and 9. In the current year an impairment charge of £353,000 was made to Intangibles Assets and charged to the Consolidated Income Statement, see note 8.

(b) Research and development ("R&D") tax credits:

R&D tax claims can be complex and require management to make significant assumptions in building the methodology for the claim, interpreting research and development tax legislation to the Group's specific circumstances, and agreeing the basis of the tax computations with HM Revenue & Customs or other tax authorities. 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 – see note 6.

Principal accounting policies

The principal accounting policies are summarised below. They have been consistently applied throughout the year covered by the Financial Statements.

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;

Notes to the Financial Statements continued

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.

Employee benefits

All employee benefit costs, notably bonuses and contributions to personal pension plans are charged to the Consolidated Statement of Comprehensive Income on an accruals basis.

Government grants

Grants are recognized when there is reasonable assurance that the Group will comply with the relevant conditions and the grant will be received. Grants that compensate the Group for expenses incurred such as research and development and staff costs are included in other operating income in the Consolidated Statement of Comprehensive Income on a systematic basis as the Group recognises as expenses the costs that the grants are intended to compensate. Grants that compensate the Group for the cost of an asset are deducted from the cost of the asset. In the current year £31,000 (2022: nil) of receivables have been included in relation to the Poolbeg's participation in the EncOVac consortium. The consortium was awarded €2.3m in non-dilutive grant funding by the Irish Government's Disruptive Technologies Innovation Fund ("DTIF") for the development of an oral vaccine candidate to a Phase I ready state. This project started in June 2023 and the Group currently makes claims on an annual basis in arrears for qualifying costs incurred.

Financial instruments

Financial instruments are classified on initial recognition as financial assets, financial liabilities or equity instruments in accordance with the substance of the contractual arrangement. Financial instruments are initially recognised when the Company becomes party to the contractual provisions of the instrument. Financial assets are de-recognised when the contractual rights to the cash flows from the financial asset expire or when the contractual rights to those assets are transferred. Financial liabilities are de-recognised when the obligation specified in the contract is discharged, cancelled or expired.

Financial assets

Cash and cash equivalents

Cash and cash equivalents comprise bank current account balances and short-term deposits with a maturity of three months or less. Amounts are readily convertible to a known amount of cash and are subject to an insignificant risk of change in value.

Trade and other receivables

Trade and other receivables have fixed or determinable payments that are not quoted in an active market, are measured at initial recognition at fair value, and are subsequently measured at amortised costs using the effective interest method less impairment. Trade and other receivables are reduced by appropriate allowances for estimated irrecoverable amounts. Interest income is recognised by applying the effective interest rate, except for short-term receivables when the recognition of interest would be immaterial.

Impairment of financial assets

At each statement of financial position date, financial assets are assessed for indicators of impairment. Financial assets are impaired if indications exist that events have occurred after the initial recognition of the financial asset that estimated future cash flows have been impacted. If any such indication exists, the recoverable amount of the asset is estimated in order to determine the extent of the impairment loss. Where the asset does not generate cash flows that are independent from other assets, the Company estimates the recoverable amount of the cash-generating unit to which the asset belongs. Any impairment loss arising from the review is charged to the statement of comprehensive income whenever the carrying amount of the asset exceeds its recoverable amount.

IFRS 9 requires the Company to make an assessment of expected credit losses relating to loans to subsidiary companies. An expected credit loss model has been used which takes into account the probability of default, the exposure at default and the loss given default at the year end. The Company defines default as the performance against plans, forecasts and the overall progress of R&D programmes towards monetisation.

The Company does not expect loans to be recalled within the next 24 months and nor would amounts be available to repay on demand and therefore the Company has considered this in calculating the expected credit loss. The probability of default is considered to be low when considering the performance of the subsidiary companies. The potential recoverable amount has been estimated based on a probability weighted cashflow model. Cashflow assumptions include forecast future licence payments, the amount and timing of which are uncertain. The Company does not believe that there is a significant risk of default and therefore has not recognised a loss provision in the current year.

Financial liabilities

Trade and other payables

Trade and other payables are initially measured at their fair value and are subsequently measured at their amortised cost using the effective interest rate method except for short-term payables when the recognition of interest would be immaterial.

Foreign currency translation

The Company translates foreign currency transactions into its functional currency, £, at the rate of exchange prevailing at the transaction date. Monetary assets and liabilities denominated in foreign currencies are translated into the functional currency at the rate of exchange prevailing at the Statement of Financial Position date. Exchange differences arising are taken to the Statement of Comprehensive Income. Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates at the dates of the initial transactions.

All Group entities have a functional currency of £.

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 data – 10 years
- Acquired licences – once in use, over the term of the licence
- Patents – once in use, over the term of the patent
- Trademarks – 10-20 years

Investment in subsidiaries

Investments in subsidiaries are stated at cost less impairment. Investment in subsidiaries are subject to annual impairment review, with any impairment charge being recognised in the Statement of Comprehensive Income.

Impairment

At each Statement of Financial Position date, the Company reviews the carrying amounts of its investments and acquired intangible assets to determine whether there is any indication that those assets have suffered an impairment loss. If any such indication exists, the recoverable amount of the asset is estimated in order to determine the extent of the impairment loss. Any impairment loss arising from the review is charged to the Statement of Comprehensive Income whenever the carrying amount of the asset exceeds its recoverable amount.

The Group assesses each asset or cash-generating unit annually to determine whether any indication of impairment exists. Where an indicator of impairment exists, a formal estimate of the recoverable amount is made, which is considered to be the higher of the fair value less costs to sell and value in use. These assessments require the use of estimates and assumptions such as discount rates, future capital requirements, general risks affecting the pharmaceutical industry and other risks specific to the individual asset. Fair value is determined as the amount that would be obtained from the sale of the asset in an arm's length transaction between knowledgeable and willing

Notes to the Financial Statements continued

parties. Fair value is generally determined as the present value of estimated future cash flows arising from the continued use of the asset, using assumptions that an independent market participant may take into account. Cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. Assets are grouped into the smallest group that generate cash inflows are independent of other assets.

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.

Share based payments

The Company has issued share options as an incentive to certain senior management. The fair value of options granted is recognised as an expense with a corresponding credit to the share-based payment reserve. The fair value is measured at grant date and spread over the period during which the awards vest.

For equity-settled share-based payment transactions, the goods or services received and the corresponding increase in equity are measured directly at the fair value of the goods or services received, unless that fair value cannot be estimated reliably. If it is not possible to estimate reliably the fair value of the goods or services received, the fair value of the equity instruments granted as calculated using the Black-Scholes model is used as a proxy.

The Company has issued warrants to advisers and certain senior management in payment or part payment for services provided to the Group. The fair value is measured at grant date and spread over the period during which the warrants vest. The fair value is measured using the Black-Scholes model if the fair value of the services received cannot be measured reliably.

The fair value of share-based payments is measured by use of valuation models, which take into account conditions attached to the vesting and exercise of the equity instruments. The expected life used in the model is adjusted; based on management's best estimate, for the effects of non-transferability, exercise restrictions and behavioural considerations. The share price volatility percentage factor used in the calculation is based on historical share price performance of a group of peer companies as historical share price performance was not available for the Company on the date of grant.

3 Segmental information

The Board considers there to be only a single operating segment: pharmaceuticals. All areas of the business are engaged in the development of a range of pharmaceutical products. Performance information is reported as a single business unit to the executive management team, who are responsible for reviewing the Group's management information. The Chief Executive Officer and Chief Financial Officer are considered to be the chief operating decision makers.

The Group did not generate revenue during the year or prior year. In addition to £31,000 (2022: nil) of grant receivables (see note 2), other operating income includes £336,000 (2022: £278,000) as a result of the recharge of facilities and staff costs under cost sharing arrangements. This is unrelated to the Group's core business and non-recurring in nature and as a result is disclosed below the gross profit line similar to the administrative expenses to which the recharges relate.

Location of non-current assets

	2023	2022
	£'000	£'000
UK	1,649	1,862
Other countries	281	272
Total non-current assets	1,930	2,134

Non-current assets consist of intangible assets. Acquired intangible assets are classified under the location where the subsidiary holding the intangible asset is incorporated.

4 Operating loss

	2023 £'000	2022 £'000
Operating loss is stated after charging:		
Fees payable to the Company's auditor for audit of the Company's annual accounts	25	20
Fees payable to the Company's auditor and its associates for other services:		
The audit of the Company's subsidiaries pursuant to legislation	5	4
Amortisation of intangible assets	26	26
Foreign exchange losses	11	33

5 Employees

The Group's average number of employees during the year was as follows:

Group	2023 Number	2022 Number
Directors	7	6
Research and development	3	2
Administrative	5	4
	15	12

Aggregate remuneration comprised:

	Group 2023 £'000	Group 2022 £'000	Company 2023 £'000	Company 2022 £'000
Wages and salaries	1,798	1,313	272	278
Social security costs	188	134	15	17
Pension costs	85	69	5	5
Other benefits	13	13	–	–
Share based payments – directors	50	429	–	–
Total employee costs	2,134	1,958	292	300

Details of the share options and warrants issued to Directors are included in the Group Directors' Report. Details of remuneration paid to Directors is included in note 15.

Highest paid director

Group's highest paid director, year to 31 December 2023:

Director	Base Salary and Fees £'000	Bonuses £'000	Pension Contributions £'000	Other Benefits £'000	2023 Total £'000	2022 Total £'000
Jeremy Skillington	250	83	25	4	362	310

Notes to the Financial Statements continued

6 Taxation

The current year tax credit is made up as follows:

	2023 £'000	2022 £'000
Current tax:		
Corporation tax on losses for the year	–	–
Prior periods adjustment in respect of research and development tax credits	(424)	(91)
Current year research and development tax receivable	(150)	–
Tax credit in Income Statement	574	91

A reconciliation of the expected tax benefit computed by applying the tax rate applicable in the primary jurisdiction, the United Kingdom, to the loss before tax to the actual tax credit is as follows:

	2023 £'000	2022 £'000
Loss before tax	(4,505)	(4,777)
Tax credit at normal rate of UK corporation tax of 25%/19%	(1,126)	(908)
Effect of:	–	
Prior period adjustments	(424)	(91)
Losses unutilised	678	744
Expenses not deductible for tax purposes	19	52
Enhanced R&D relief	18	–
Differences in overseas taxation rates	261	112
Current tax credit for the year	(574)	(91)

The Group has tax losses of up to £8,283,000 (2022: £4,472,000) to carry forward against future profits. The deferred tax asset on tax losses at 25% of £2,071,000 (2022: £1,118,000) has not been recognised due to the uncertainty of the recovery.

The Group qualifies for HMRC's SME R&D tax relief scheme which allows it to deduct an extra 86% (130% up to 31 March 2023) of its qualifying costs against its tax position. As the Group is loss making it elects to claim receivable tax credits under the scheme, which are calculated as 14.5% (10% from 1 April 2023 if a loss making company is not classified as R&D intensive) of the surrenderable loss, instead of carrying forward the enhanced R&D relief as additional tax losses.

7 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

Date	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.

8 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.

Notes to the Financial Statements continued

9 Investment in subsidiaries

Company	Equity in subsidiary companies £'000	Subsidiary funding £'000	Total £'000
Cost			
At 1 January 2022	1,740	1,520	3,260
Additions	429	4,417	4,846
At 31 December 2022	2,169	5,937	8,106
Additions	50	4,247	4,297
At 31 December 2023	2,219	10,184	12,403
Impairment			
Balance at 31 December 2022	-	-	-
Balance at 31 December 2023	-	-	-
Net book value			
At 31 December 2023	2,219	10,184	12,403
At 31 December 2022	2,169	5,937	8,106

The current year additions include share-based payment charges of £50,000 (2022: £429,000) for share options granted to employees of subsidiary companies.

Funding additions relate to the advancement of loans to Poolbeg Pharma (UK) Limited (formerly ORPH Pharma IP Company Limited) and Poolbeg Pharma (Ireland) Limited to fund the operations of those companies including the R&D costs incurred. Recoverability of the loans and the carrying value of the investments is directly linked to the success or failure of the development of the subsidiaries' pipeline of assets. The carrying value of these investments are held at cost and will be reviewed at each reporting date for signs of impairment.

List of subsidiary companies:

Subsidiary company	Activities	Company Number	Incorporation	2023 % holding	2022 % holding
Poolbeg Pharma (Ireland) Limited	Pharmaceuticals R&D and management services	698030	Ireland	100	100
Poolbeg Pharma (UK) Limited	Pharmaceuticals R&D	13279216	UK	100	100
OP Holdco 2021 Limited	Dormant	13356328	UK	100	100

ORPH Pharma IP Company Limited was renamed to Poolbeg Pharma (UK) Limited on 22 June 2023.

List of registered offices:

Company	Registered Office Address
Poolbeg Pharma (Ireland) Limited	4th Floor, Fitzwilliam Hall, Fitzwilliam Place, Dublin 2, D02 T292, Ireland
Poolbeg Pharma (UK) Limited	Queen Mary BioEnterprises Innovation Centre, 42 New Road, London, E1 2AX, England
OP Holdco 2021 Limited	Queen Mary BioEnterprises Innovation Centre, 42 New Road, London, E1 2AX, England

10 Trade and other receivables

	Group	Group	Company	Company
	2023	2022	2023	2022
	£'000	£'000	£'000	£'000
Prepayments and accrued income	669	878	231	274
Grant receivable	31	–	–	–
VAT recoverable	53	84	23	27
R&D tax credit	574	–	–	–
Trade and other receivables	1,327	962	254	301

11 Cash and cash equivalents

	Group	Group	Company	Company
	2023	2022	2023	2022
	£'000	£'000	£'000	£'000
Bank current accounts	2,260	1,069	1,637	629
Short term notice deposits	9,911	15,124	9,911	15,124
Cash and cash equivalents	12,171	16,193	11,548	15,753

12 Issued share capital and other reserves

Details of ordinary shares of 0.02p each issued are in the table below:

	Number of ordinary shares	Share Capital £'000
At 1 January 2022 & 31 December 2022	500,000,000	100
At 31 December 2023	500,000,000	100

No shares were issued during the year. As is permitted under the Companies Act 2006, the Company does not have authorised share capital.

Other reserves

Share capital represents the cumulative par value arising upon issue of ordinary shares of 0.02p each.

Share premium represents the consideration that has been received in excess of the nominal value on issue of share capital.

Share-based payment reserve relates to the charge for share based payments in accordance with IFRS 2.

The merger reserve was created on the acquisition of Poolbeg Pharma (UK) Limited (formerly ORPH Pharma IP Company Limited) as part of the demerger from hVIVO plc (formerly Open Orphan plc). Consideration on the acquisition was satisfied by the issuance of shares. Under section 612 of the Companies Act 2006, the premium on these shares has been included in a merger reserve.

Accumulated deficit represents losses accumulated in the current year and prior periods.

13 Share-based payments

The Company has issued share options as an incentive to certain senior management. In addition, the Company has issued warrants to senior management and advisers in payment or part payment for services provided to the Group. All share options granted were granted under individual agreements and are subject to market and service vesting conditions. The Company does not, as yet, have a share option plan in place. All warrants granted were granted under individual agreements.

Each share option and warrant converts into one ordinary share of Poolbeg Pharma plc on exercise and are accounted for as equity-settled share-based payments. The equity instruments granted carry neither rights to dividends nor voting rights.

Notes to the Financial Statements continued

Share options and warrants in issue:

	Share options	Weighted average exercise price	Warrants	Weighted average exercise price
1 January 2022 & 31 December 2022	36,000,000	13.3p	829,181	10.0p
31 December 2023	36,000,000	13.3p	829,181	10.0p

Further details on the vesting conditions attached to the share options granted are set out in the Group Directors' Report. No share options or warrants were issued during the current year, see note 18 for share options issued after the reporting period. The fair value was estimated at the date of grant using the Black-Scholes pricing model, taking into account the terms and conditions attached to the grant.

In 2021 a total of 36,000,000 share options exercisable at a weighted average price of £0.133 were granted. The share options outstanding as at 31 December 2023 have a weighted remaining contractual life of 7.5 years with exercise prices ranging from £0.10 to £0.15.

In 2021, a total of 829,181 warrants exercisable at a weighted average price of £0.10 were granted. The warrants outstanding as at 31 December 2023 have a weighted remaining contractual life of 2.6 years with an exercise price of £0.10.

The value of share options and warrants charged to administrative expenses in the Statement of Comprehensive Income is as follows:

	2023 £'000	2022 £'000
Share options	50	429
Total	50	429

14 Trade and other payables

	Group 2023 £'000	Group 2022 £'000	Company 2023 £'000	Company 2022 £'000
Trade payables	79	293	24	35
Accrued expenses	846	623	315	115
Other payables	9	4	–	2
Social security costs and other taxes	52	46	4	4
Trade and other payables	986	966	343	156

15 Related party transactions

Compensation of key management personnel of the Group

Key management are those persons having authority and responsibility for planning, controlling and directing the activities of the Company. In the opinion of the Board, the Company's key management are the Directors of Poolbeg Pharma plc.

Amounts included in the Financial Statements, in aggregate, by category of related party are as follows:

	Group	Group	Company	Company
	2023	2022	2023	2022
	£'000	£'000	£'000	£'000
Directors				
Directors' remuneration (short term benefits)	817	723	183	170
Directors' remuneration (pension cost)	40	40	–	–
Share based payments	50	429	–	–
Other fees	23	15	23	15
Total	930	1,207	206	185

Shares purchased by Directors

No shares were purchased by Directors during the year. See note 18 for shares purchases after the reporting period.

Other transactions with Directors

The following amounts were charged by entities related to the Directors:

	Group	Group	Company	Company
	2023	2022	2023	2022
	£'000	£'000	£'000	£'000
Directors				
Office facilities costs	4	4	–	–
Total	4	4	–	–

Office facilities costs relate to the recharge of expenses incurred in relation to the Dublin office. These are recharged at cost.

See note 18 for share options issued to directors after the reporting period.

Transactions with Group companies

Poolbeg Pharma plc has provided loans to its subsidiary companies (see note 9). The amounts due are subject to interest and it has been confirmed by the Directors that the loans will not be recalled within the next 12 months.

The following loan balances were due at year end:

	2023	2022
	£'000	£'000
Subsidiary company		
Poolbeg Pharma (UK) Limited	5,557	3,493
Poolbeg Pharma (Ireland) Limited	4,627	2,444
Total	10,184	5,937

The Company charged the following interest to subsidiary companies during the year:

	2023	2022
	£'000	£'000
Subsidiary company		
Poolbeg Pharma (UK) Limited	371	123
Poolbeg Pharma (Ireland) Limited	298	100
Total	669	223

Notes to the Financial Statements continued

The Company made the following management recharges to subsidiary companies during the year:

	2023	2022
Subsidiary company	£'000	£'000
Poolbeg Pharma (UK) Limited	22	72

Transactions were undertaken on normal commercial terms in the ordinary course of the Company's business.

The Company had the following management recharges included in accrued income at year end:

	2023	2022
Subsidiary company	£'000	£'000
Poolbeg Pharma (UK) Limited	6	25

Outstanding balances at the year-end are unsecured, interest free and settlement occurs in cash.

16 Financial risk management

The Group is exposed to risks that arise as a result of its use of financial instruments. Details of the financial instruments generated during the Group's activities are below:

Categories of Group and Company financial instruments

	Group	Group	Company	Company
	2023	2022	2023	2022
	£'000	£'000	£'000	£'000
Financial assets (all at amortised cost):				
Cash and cash equivalents	12,171	16,193	11,548	15,753
Trade and other receivables (excluding prepayments)	725	144	67	87
Total financial assets	12,896	16,337	11,615	15,840
Financial liabilities:				
At amortised cost				
Trade and other payables	986	966	343	156
Total financial liabilities	986	966	343	156
Net	11,910	15,371	11,272	15,684

The Board considers that the carrying values of all financial assets and liabilities shown above to be the fair value of the Group's and the Company's assets and liabilities.

Policies and objectives

The Group's operations expose it to some financial risks arising from its use of financial instruments, the most significant ones being liquidity, market risk and credit risk. The Board of Directors is responsible for the Group and Company's risk management policies and whilst retaining responsibility for them it has delegated the authority for designing and operating processes that ensure the effective implementation of the objectives and policies to the Group's finance function. The main policies for managing these risks are as follows:

Liquidity risk

The Group is not subject to any externally imposed capital requirement, accordingly the Group's objectives when managing capital are to safeguard the ability to continue as a going concern in order to provide returns for shareholders and benefits to other stakeholders and to maintain an optimal capital structure to reduce the cost of capital. Working capital forecasts are prepared to ensure the Group has sufficient funds to complete contracted work commitments.

The following table shows the maturity profile of current liabilities of the Group:

	Less than 1 month £'000	Between 1 and 3 months £'000	Between 3 and 6 months £'000	Between 6 and 12 months £'000	Total £'000
2023					
Current liabilities	236	553	197	–	986

	Less than 1 month £'000	Between 1 and 3 months £'000	Between 3 and 6 months £'000	Between 6 and 12 months £'000	Total £'000
2022					
Current liabilities	539	318	109	–	966

The following table shows the maturity profile of current liabilities of the Company:

	Less than 1 month £'000	Between 1 and 3 months £'000	Between 3 and 6 months £'000	Between 6 and 12 months £'000	Total £'000
2023					
Current liabilities	63	147	133	–	343

	Less than 1 month £'000	Between 1 and 3 months £'000	Between 3 and 6 months £'000	Between 6 and 12 months £'000	Total £'000
2022					
Current liabilities	75	32	49	–	156

Capital management

The Group considers its capital to be its ordinary share capital, share premium, other reserves and accumulated deficit. The Group manages its capital to ensure that entities within the Group will be able to continue individually as going concerns, while maximising the return to shareholders through the optimisation of debt and equity balances. The Group manages its capital structure and makes adjustments to it, in the light of changes in economic conditions. To maintain or adjust its capital structure, the Group may adjust or issue new shares or raise debt. On a regular basis, management receives financial and operational performance reports that enable continuous management of assets, liabilities and liquidity.

Market risk

Market risk arises from the use of interest bearing financial instruments and represents the risk that future cash flows of a financial instrument will fluctuate as a result of changes in interest rates. It is the Group's policy to ensure that significant contracts are entered into in its functional currency whenever possible and to maintain the majority of cash balances in the functional currency of the Company. The Group considers this policy minimises any unnecessary foreign exchange exposure. In order to monitor the continuing effectiveness of this policy the Board reviews the currency profile of cash balances and managements accounts.

During the year, the Group earned interest on its cash and cash equivalents held on deposit. The effect of a 1% change in interest rates obtainable during the year on cash and cash equivalents balances would be to increase or decrease the Group loss before tax by £139,000.

In addition to cash balances maintained in £, the Group had balances in € at year-end. A theoretical 10% adverse movement in the period end £:€ exchange rate would lead to an increase in the Group loss before tax by £32,000 with a corresponding reduction in the Group loss before tax with a 10% favourable movement.

Credit risk

Credit risk is the risk that the counterparty will default on its contractual obligations resulting in financial loss. Credit risk arises from cash and cash equivalents and from exposure via deposits with the Group and Company's bankers. For cash and cash equivalents, the Group and Company only uses recognised banks with high credit ratings.

Notes to the Financial Statements continued

17 Capital commitments and contingencies

The Group has no material capital commitments at the year end.

As part of its regular business the Group enters into licence and collaboration agreements that can contain contingent sales royalty and milestone payments and/or work programme commitments. The payment of royalty and milestone payments under these agreements is entirely dependent on the successful development and commercialisation of the products to which they relate.

18 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.

Company Information

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Jeremy Skillington – CEO
Ian O’Connell – CFO
Eddie Gibson - Non-Executive Director
Brendan Buckley - Non-Executive Director
Luke O’Neill – Non-Executive Director

Company Secretary

Beach Secretaries Limited

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