POOLBEG PHARMA

Poolbeg Pharma plc

Annual Report 2022

A LEADING BIOPHARMA SPECIALISING IN INFECTIOUS & OTHER PREVALENT DISEASES

Significant progress made & continuing with strong momentum

2022 – Year in Review

- AI Deal with CytoReason & Influenza AI Model Build Complete
- AI Deal with OneThree Biotech & RSV drug targets & treatments identified
- License for RNA-Based Immunotherapy for RVIs – POLB 002
- License of Melioidosis Vaccine Candidate – POLB 003
- License to Develop Oral Vaccine Platform and successful €2.3m grant award
- POLB 001 LPS Human Challenge Trial Successfully Completed with Positive Data
- POLB 001 Oncology Programme launched
- Metabolic Disease Oral Delivery Programme
- Commenced trading on OTCQB

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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 2022. Our first full year as a listed company has been one of substantial progress:

- **Successfully expanded and diversified our pipeline**

We have transformed and broadened our pipeline by adding complementary new technologies and indications in infectious and other prevalent diseases. This included securing exclusive licences for POLB 002 (an RNA-based immunotherapy for respiratory virus infections), POLB 003 (an intramuscular vaccine candidate to prevent Melioidosis) and for use of AnaBio Technologies' ("AnaBio") microencapsulation and nanoencapsulation technology to develop oral vaccines and for use in metabolic syndrome related diseases including obesity, pre-diabetes and diabetes. In addition, Poolbeg commenced exciting collaborations with two leading biology driven Artificial Intelligence ("AI") specialists.

- **Significant progress on R&D programmes**

During 2022, highlights include the completion of our bacterial lipopolysaccharide "LPS" human challenge trial for POLB 001 which demonstrated that POLB 001 was safe and well tolerated and had a potent effect in systemic and localised inflammatory response in a dose dependent manner. This was a milestone achievement for Poolbeg as it demonstrated POLB 001's expected utility in severe influenza.

Following finalisation of our AI collaboration agreements in Q1 2022, we made excellent progress on the AI programmes before year end.

- Poolbeg's novel respiratory syncytial virus ("RSV") focused AI programme with partner OneThree Biotech yielded multiple novel RSV drug targets. Following the discovery of these drug targets, the collaboration identified a number of promising RSV drug candidates and we now plan to rapidly bring these forward to lab-based validation.
- Poolbeg's Influenza focused AI programme with partner CytoReason hit a major milestone during the year as the construction of the computational artificial intelligence influenza disease model was completed in November 2022.

- **Excellent corporate progress**

In March 2022, we announced the trading of our shares on the OTCQB Venture Market in the United States under the ticker: POLBF. We believe that this is a useful way of raising awareness of, and access to, Poolbeg shares for US investors.

In line with our strategy of targeting non–dilutive funding to assist in progressing our pipeline products, in November 2022 a Poolbeg-led consortium was awarded €2.3m in non-dilutive funding to progress an Oral Vaccine Platform.

During the year, Poolbeg also added select experienced hires to our team which has bolstered our capabilities in core areas such as business development and will help drive further rapid development of the Company.

Financial

Poolbeg is well capitalised for our current needs, with a cash balance of £16.2m (2021: £20.9m) at year end. The loss for the year amounted to £4.7m (2021: £2.3m) and comprises R&D expenses £2.2m (2021: £0.4m), administrative expenses £3.1m (2021: £2.0m) and other income and tax rebates of £0.6m (£0.1m). Poolbeg's model seeks to efficiently allocate capital to high potential opportunities which we can secure on attractive terms, that can be de-risked effectively, are in a market and indication where there is a clear opportunity for onward licensing / partnering and which we believe can generate a strong return on the capital invested.

Outlook

The momentum generated during 2022 has continued into the current year. Post year end, we have made important progress on POLB 001, reporting positive data from the LPS human challenge trial with a marked reduction in both systemic and localised inflammatory response in a manner that suggests expected utility in treating life-threatening infections such as severe influenza and supports continued development in the Cytokine Release Syndrome ("CRS") associated with other acute inflammatory conditions.

A long-term objective for Poolbeg continues to be to evaluate POLB 001's potential in additional indications to fully unlock the potential value of the molecule and strengthen Poolbeg's position for partnering and out-licensing. In line with this objective, in January 2023, we announced the strategic expansion of POLB 001 into oncology, as a potential treatment option for CRS experienced by up to 95% of cancer patients receiving CAR T cell therapy. Clinical trial enabling activities are underway to progress towards trial initiation in CAR T cell patients in 2024.

2022 was a year of significant progress for Poolbeg, we strategically expanded our pipeline and successfully achieved our stated objectives on time and in line with our disciplined capital allocation approach. We enter 2023 well capitalised with a fully diversified pipeline and positive data from our first clinical trial for our potential blockbuster treatment for severe influenza. Poolbeg is poised to maximise the opportunities within its portfolio to deliver sustainable value for shareholders by becoming a one-stop-shop for pharma and biotech seeking programmes to in-license. We look forward to continued progress in 2023.

Cathal Friel
Chairman

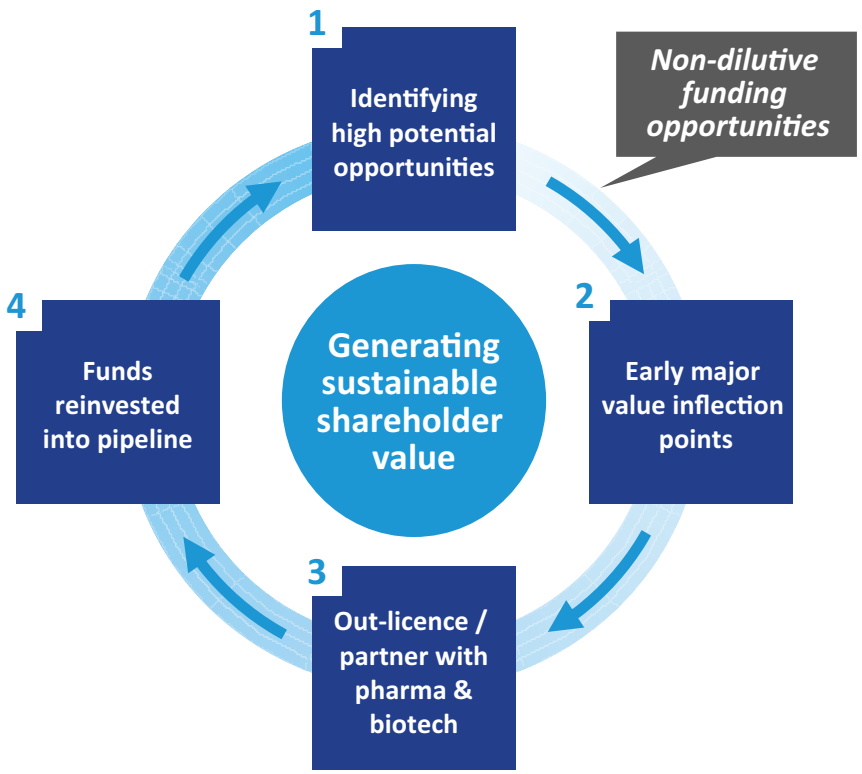
29 March 2023

STRATEGIC REPORT:
CEO's Operations Review

Poolbeg's Focus and Positioning

Poolbeg specialises in the development of innovative medicines to address the unmet need in infectious and other prevalent diseases. Poolbeg has a disciplined portfolio approach to mitigate risk, accelerate drug development and enhance investor returns. We aim to simultaneously advance multiple programmes faster and more cost effectively than the conventional biotech model. By advancing multiple programmes concurrently in smart, cost-effective clinical trials, we can rapidly generate early human safety and efficacy data to enable partnering or out-licensing to pharma / biotech, with the funds generated reinvested into the pipeline.

In the wake of the COVID-19 pandemic, global biopharma has refocused upon developing vaccines and treatments targeting infectious diseases and it has become one of the fastest growing pharma markets; expected to exceed $250bn by 2025. Through opportunistic identification of assets which complement Poolbeg's existing pipeline, we are now progressing programmes in oncology and metabolic syndromes; adding disease areas with significant addressable markets to our pipeline.



Poolbeg's four steps to generating sustainable shareholder value

Poolbeg, with its growing pipeline is well positioned to capitalise on the themes within global pharma; pharma recognise the need to fill their pipelines with de-risked drug candidates across many disease areas, particularly as many existing blockbuster drugs are reaching the end of their patent lives. There is a clear trend for more in-licensing, with a focus on drug candidates with existing human data.

Poolbeg is determined to capitalise on this opportunity by leveraging the most cutting-edge technology and utilising smart clinical trial design to generate strong early human efficacy data in order to attract pharma and biotech partners for its assets. Global pharma trends highlight that over 90% of licensing deals occur in pre-Phase II assets and Poolbeg aims to become a one-stop-shop for pharma and biotech companies seeking these de-risked assets. Poolbeg continues to engage with pharma and biotech companies with regards to potential out-licensing opportunities for our assets.

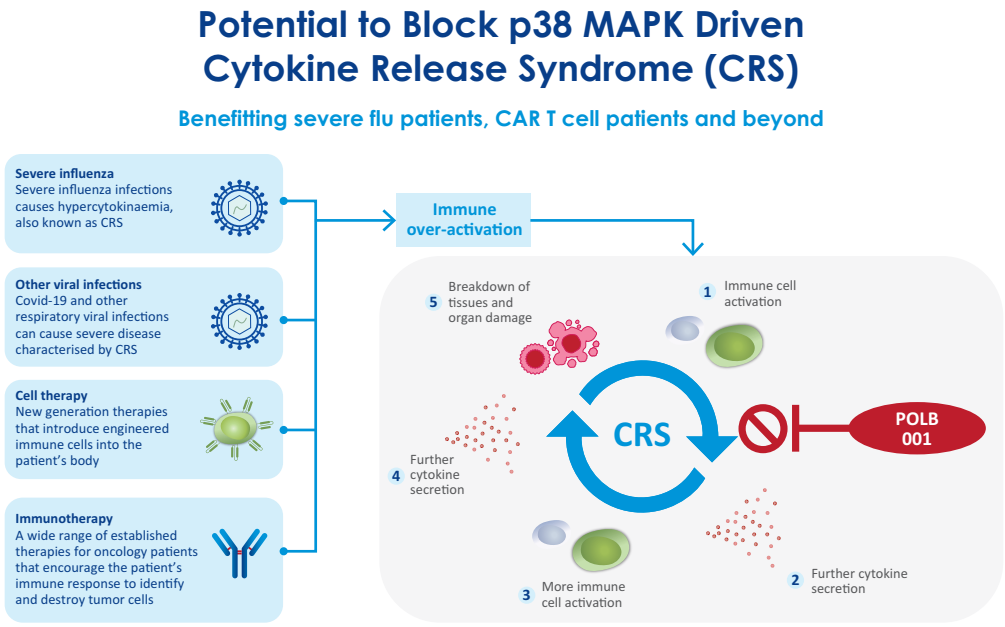
The team are also evaluating potential in-licensing options to add to our pipeline. Key selection criteria include compelling data, the ability to license on attractive terms, the opportunity to quickly de-risk and create value with near term value inflection points; the market opportunity, the appeal of the asset to future partners, and the potential future return expected from partnering. Additionally, the potential for non-dilutive grant funding to support development is also a key selection criterion and Poolbeg proved its ability to secure such funding in 2022, as a Poolbeg-led consortium was awarded €2.3m in non-dilutive funding to progress its Oral Vaccine Platform.

Pipeline Development

POLB 001 – Severe Influenza

A potential blockbuster small molecule immunomodulator being developed to address the unmet medical need arising from severe influenza and other acute inflammatory conditions. In 2022, Poolbeg successfully completed an LPS human challenge trial to provide key human data on its potential in selectively inhibiting the hyperinflammatory response which can often be life threatening in severe influenza and other acute inflammatory conditions.

Unlike other influenza treatments, POLB 001 targets the hosts immune response rather than the viral infection itself by selectively inhibiting the body's overwhelming inflammatory response (Cytokine Storm) while leaving the necessary immune functions intact to fight the infection. This contrasts from other immunomodulatory approaches, such as steroids, which affect both the beneficial and the damaging immune responses. Cytokines, produced to stimulate and shape the immune response, can result in a Cytokine Storm or Cytokine Release Syndrome ("CRS") when overexpressed, sweeping through the body re-programming white blood cells and resulting in tissue damage, shutting down circulation and other essential organs and potentially leading to death.



The role of POLB 001 in addressing CRS

A randomised, double-blind, placebo-controlled, multiple dose, bacterial lipopolysaccharide ("LPS") human challenge trial in 36 healthy volunteers to assess the potential efficacy of POLB 001 in treating the hyperinflammatory responses associated with severe influenza and other acute inflammatory conditions completed in December 2022. The positive initial results from the trial were received in January 2023 and the full results were made available in March 2023. These showed that treatment with POLB 001 resulted in a highly significant reduction in p38 MAP kinase driven cytokines and caused a marked reduction in multiple markers of systemic and local inflammation compared with placebo in a dose dependent manner. POLB 001 was shown to be safe and well tolerated, with the results demonstrating POLB 001's expected utility in severe influenza.

STRATEGIC REPORT:
CEO's Operations Review continued

Systemic Inflammatory Response

The typical LPS-induced increase in plasma cytokine levels (TNF-α, IL-6, and IL-8) was reduced by between 57-81% across all cytokines in subjects treated with 70 mg or 150 mg POLB 001 (all highly significant P values <0.0003).

POLB 001 was shown to have the following dose dependent effects:

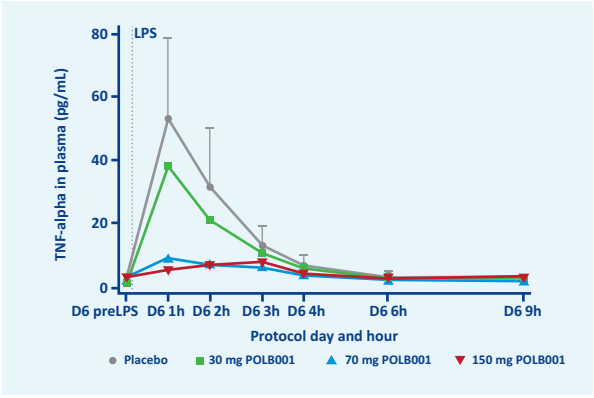
- blunted the LPS associated rise in heart rate across all dose groups (P<0.001)
- reduced body temperature and C-reactive protein ("CRP") levels, a clinically used nonspecific marker of inflammation
- target engagement causing a dose dependent reduction in p38 phosphorylation activation status in white blood cells

Localised Inflammatory Response

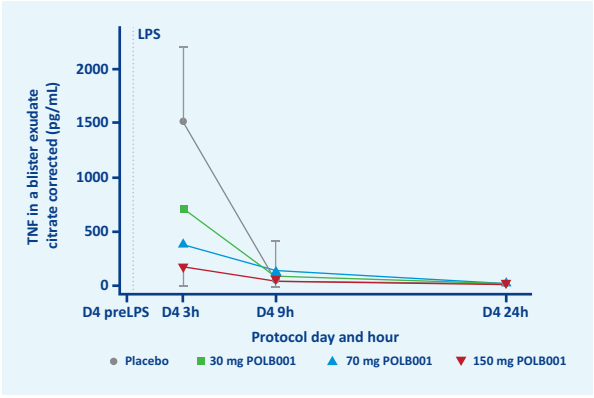
POLB 001 infiltration into inflamed tissues blocked localised cytokine release and reduced invasion of tissue damaging inflammatory cells as reflected by:

- complete ablation of tissue damaging neutrophil accumulation within the inflamed tissue
- LPS-induced rise in intermediate monocytes (inflammatory mediators) was substantially lower in subjects treated with 70 mg or 150 mg POLB 001
- a highly significant reduction in TNF-α in subjects treated with 150 mg POLB 001 of 65.1% (P<0.0009)

POLB 001 Dampens Systemic Cytokine Expression
TNF-α in plasma (pg/ml)



POLB 001 Dampens Localised Cytokine Expression
TNF-α in blister (pg/ml)

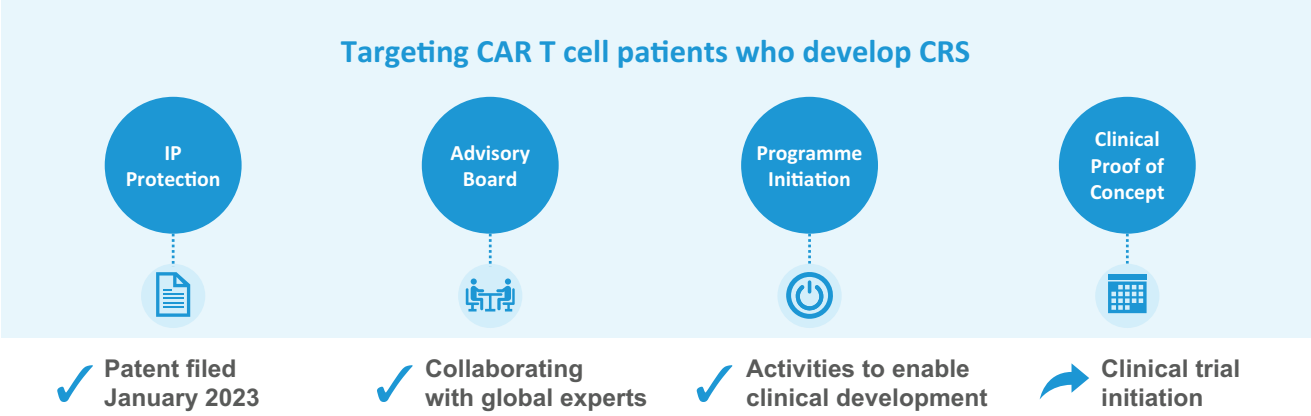


POLB 001 caused a highly significant reduction in systemic and localised p38 MAP kinase driven cytokines in an LPS human challenge trial

POLB 001 - Oncology

Post year-end, we announced a strategic expansion of POLB 001 into oncology as a potential treatment option for the CRS experienced by cancer patients as a side effect of this type of immunotherapy. A significant number of CAR T cell patients suffer treatment related side effects, including Cytokine Release Syndrome (which can be life threatening) with some cell therapies inducing these effects in up to 95% of patients. Although this extends beyond Poolbeg's infectious disease focus, the potential benefit of POLB 001 to these patients merited a strategic expansion of the asset into this field.

A long-term strategic objective continues to be the evaluation of POLB 001's potential in further indications in order to fully unlock the value of the molecule. This expansion to oncology unlocks a significant new market opportunity for POLB 001 in addition to severe influenza and strengthens our position in partnering and out-licensing discussions. We are now progressing oncology clinical trial enabling activities with the aim of initiating a trial in CAR T cell patients during 2024. Further oncology-related data, regulatory feedback and non-clinical development updates are expected during 2023.



POLB 001 Oncology Programme Initiated

POLB 002

We successfully in-licensed a first-in-class broad spectrum RNA-based immunotherapy for respiratory virus infections from the University of Warwick, which is being developed by Poolbeg as POLB 002. Administered intra-nasally, this RNA-based immunotherapy works by triggering nasal cells into an antiviral state to protect against an infecting virus. At the same time, it also blocks the cells from making more virus by directly preventing its replication. The combination of these actions can reduce infectious viral loads and improve disease symptoms. Importantly, in-vivo data confirms that POLB 002 targets a broad spectrum of respiratory virus infections, offering pan-viral protection from respiratory virus infections including influenza, respiratory syncytial virus ("RSV"), SARS-CoV-2 and others.

This contributes to the global interest in developing a pan-viral product which can be easily administered and distributed to treat a variety of respiratory virus infections. As a nasally administered and rapidly effective prophylactic antiviral candidate, it could potentially provide an effective solution for protecting at risk patient populations (e.g. the elderly, COPD patients, and asthmatics).

POLB 003

POLB 003 is a late preclinical stage vaccine candidate for Melioidosis, an infectious disease with a high mortality rate for which there is no approved vaccine available. The Company initially acquired an option over this vaccine candidate before successfully in-licensing POLB 003 in September 2022 from University College Dublin ("UCD") through NovaUCD, the University's knowledge transfer office.

The vaccine candidate, developed by Associate Professor Siobhán McClean and her team at UCD, is at a late pre-clinical stage and has shown promising early efficacy data in preclinical studies. Melioidosis is already widespread in SouthEast Asia, Northern Australia and India, but the warming climate is having a substantial impact on the spread of the disease to new areas such as Brazil and traditionally non-tropical areas. As a US Centers for Disease Control and Prevention ("CDC") designated biothreat, there is an increasing global need to develop effective vaccines and antibiotics to prevent and treat this disease.

Poolbeg also has the option to license a further five bacterial vaccine candidates being developed by Associate Professor McClean and her team. This includes *Escherichia coli (O157)*; a powerful toxin that can severely harm children and the elderly, leaving lasting kidney damage; *Pseudomonas aeruginosa*; a highly antibiotic resistant bacteria, which is the leading cause of morbidity and mortality in cystic fibrosis patients. As well as *Klebsiella pneumoniae* which is a prevalent issue in US Defence and healthcare settings resulting in burdensome management of complications; *Burkholderia cepacia complex*, a significant cause of hospital-acquired infections with large impact on health budgets; and *Acinetobacter baumannii* which poses a threat to immuno-compromised patients in care settings, such as cystic fibrosis patients.

Oral Vaccine Platform

The COVID-19 pandemic highlighted the shortcomings of traditional intramuscular vaccines. These include the need for cold chain delivery, the requirement for skilled medical staff to administer the vaccines, public access to designated administration sites, needle phobia and localised side effects, such as pain, numbness and subsequent infection.

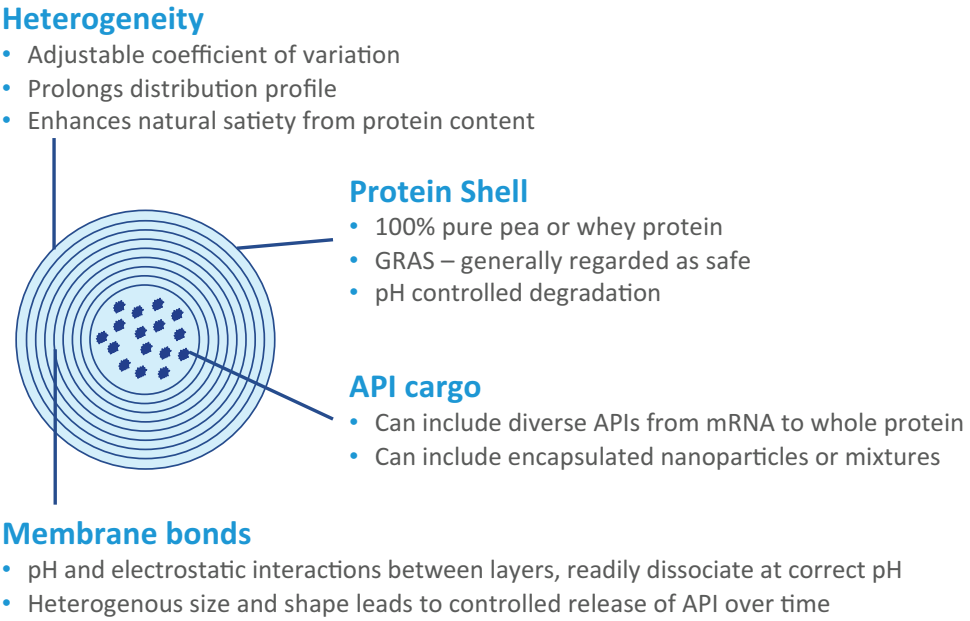
STRATEGIC REPORT:
CEO's Operations Review continued

In January 2022, Poolbeg partnered with microencapsulation and nanoencapsulation specialist AnaBio to develop an oral vaccine delivery platform, to safeguard the future of infectious disease prevention by encouraging increased vaccine uptake. Poolbeg licensed AnaBio's microencapsulation and nanoencapsulation technologies aimed at triggering 'mucosal immunity' by delivering oral vaccines to the gut, 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.

This collaboration has resulted in the creation of the EncOVac consortium, led by Poolbeg with partners AnaBio, Trinity College Dublin, and UCD. In November 2022, 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.

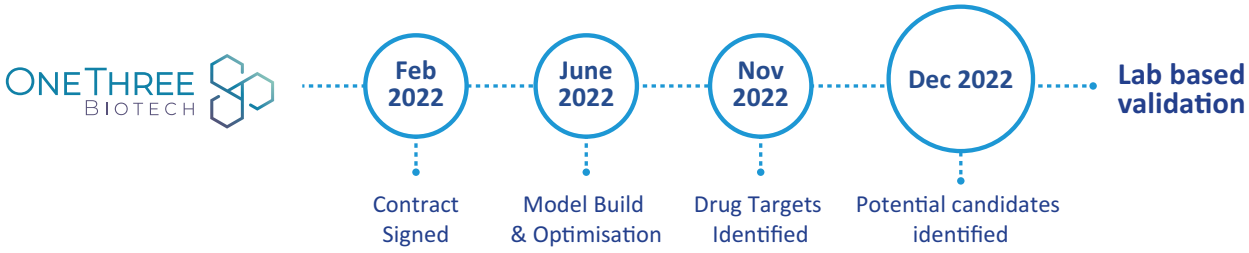
Oral Delivery Platform – Metabolic Diseases

Drawing on our growing understanding of the encapsulation technology from the Oral Vaccine Platform, Poolbeg signed an exclusive licence with InsuCaps Limited, a sister company of AnaBio Technologies to develop their patented microencapsulation and nanoencapsulation technologies in metabolic syndrome related diseases, including obesity, pre-diabetes and diabetes. We are currently working towards a proof-of-technology clinical trial to determine that a Glucagon-like Peptide 1 receptor ("GLP-1") agonist can be successfully delivered orally in humans and trial planning activities have commenced post year end. GLP-1 agonists are used to treat obesity and diabetes, and this trial has the potential to tap into an industry that will be worth an estimated $150bn by 2031.



Microencapsulation of API's (active pharmaceutical ingredients)

Artificial Intelligence ("AI") Programme - Respiratory Syncytial Virus

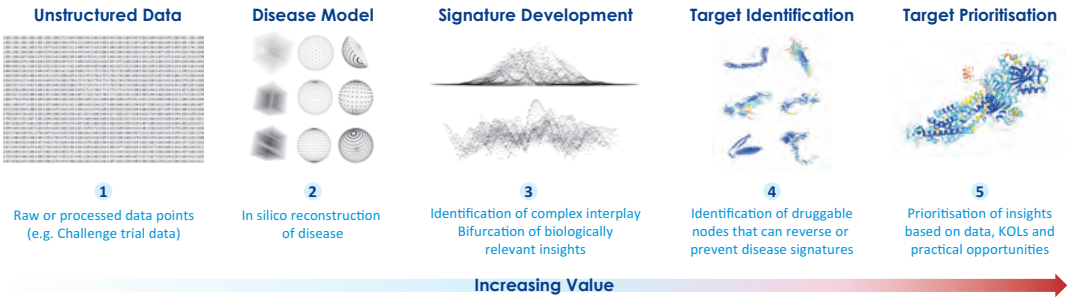


During 2022, we have seen ground-breaking developments in our efforts to use AI technologies to identify drug targets and potential treatments. It has proved a low-cost and effective way of exploring new avenues for existing and potential pipeline assets.

In February 2022, Poolbeg signed an agreement with OneThree Biotech, a biology-driven AI company, to identify new drug targets and treatments for Respiratory Syncytial Virus ("RSV"). Since initiating the collaboration, Poolbeg's scientific team has worked closely with OneThree Biotech to build a tailored AI approach that leverages Poolbeg's unique RSV human challenge trial data in order to identify disease-relevant biological pathways and potential drug targets. This is a world first programme - the first time that AI analysis has been undertaken on RSV human challenge trial data with new drug targets and candidates successfully identified.

Drug targets were successfully identified in November 2022 and based on those newly discovered drug targets; the collaboration identified a number of promising drug candidates in December 2022 to rapidly bring forward to lab-based validation to determine the full potential of these assets. This significant breakthrough has demonstrated the power of AI in speeding up drug discovery and identification and has re-emphasised our confidence in the value of our data and our technology driven programmes for our pipeline going forward.

Poolbeg has prioritised compounds with existing Phase I clinical data and which could, if successfully validated, be repositioned as novel treatments for RSV infection. Candidates with solid safety and pharmacodynamic data in humans are well positioned to rapidly enter a clinical trial to generate early human efficacy data for RSV. This is in line with Poolbeg's efficient, capital light clinical development strategy that is at the core of its ambitious growth model.



Identifying drug targets using artificial intelligence

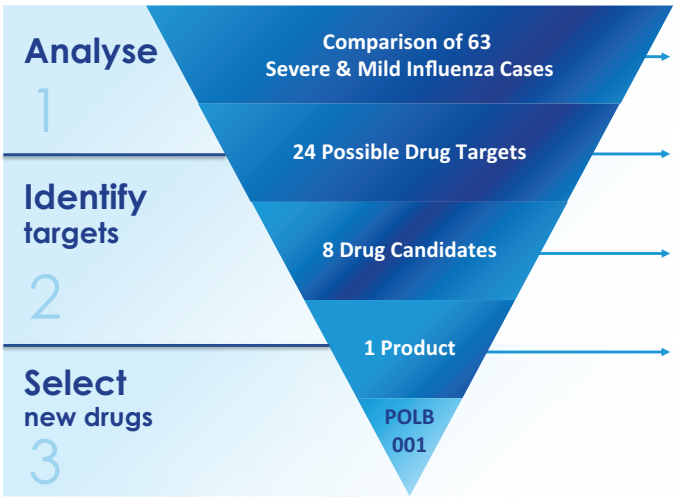
STRATEGIC REPORT:
CEO's Operations Review continued

Artificial Intelligence Programme – Influenza

In March 2022, Poolbeg signed an agreement with leading AI company, CytoReason, to provide analysis of Poolbeg's unique influenza disease progression data derived from human challenge trial samples. CytoReason has built world-class validated AI models which can extrapolate immune cell behaviour based on bulk transcriptomics, making it an ideal partner to maximise the insights of our influenza data. To date, five of the world's top ten pharma companies use CytoReason's technology including Pfizer, Sanofi, Merck KGaA and Roche.

In November 2022, the construction of the computational disease model was completed and is on track to deliver outputs in Q2 2023, which will present novel influenza drug targets.

This innovative programme is the first time that AI is being used to analyse influenza human challenge trial data. This unique data has already been used to successfully identify POLB 001 in a process which took many years to complete through manual analysis of data. AI analysis has the capacity to significantly accelerate this process.



- Samples taken from patients with severe influenza were compared against human challenge trial subjects with mild influenza
- This work identified 24 potential molecules that play a role in influenza severity, with p38 MAPK being the most important
- 40 p38 MAPK inhibitors were identified, and 8 were short-listed for detailed analysis
- Based on its superior performance and advantageous licensing terms, POLB 001 was chosen as the best candidate to take forward

Roadmap to identifying POLB 001 from human challenge trial data that AI can replicate but in a much quicker timeframe

Intellectual property

Poolbeg has a strong focus upon continually strengthening and broadening its IP portfolio; filing patents in key global territories to protect our product pipeline.

Poolbeg continuously assesses its patent portfolio and is vigilant in monitoring for instances of IP infringement. Poolbeg has a worldwide licence for POLB 001 for all uses in humans and is developing a strong IP portfolio with US patent protection in place covering the use of a wide range of p38 MAP kinase (mitogen-activated protein kinase) inhibitors for the treatment of symptoms of severe influenza and the use of POLB 001 and structurally related analogues for the treatment of hypercytokinemia and a European patent for the class of p38 MAP kinase inhibitors for use in the treatment of severe influenza.

Its patent protection 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 until 2037 ("Immunomodulators I") and the treatment of hypercytokinemia until 2038 ("Immunomodulators II"). The Immunomodulators II application also includes claims to the use of POLB 001 and other p38 MAPK inhibitors in combination with an antiviral.

The Immunomodulators I family of patents includes granted patents in Europe and the US further pending patents in the EU, the US and Japan. Even wider geographical coverage is sought via the Immunomodulators II application extending to Australia, Brazil, Canada, China, Hong Kong, Israel and Korea. In May 2022, the United States Patent & Trademark Office ("USPTO") issued a Notice of Allowance on the Immunomodulators II application and the full granting of a patent was received in March 2023. The company will seek patent term extensions (or equivalents) upon marketing approval of POLB 001, to extend further the term of protection. This means that there is ample opportunity for POLB 001 to generate substantial long-term value over the next 15 years at least, and this length of patent should be attractive to prospective acquirers / in licensees of POLB 001. The Immunomodulators I and Immunomodulators II families of patents continue to progress through the examination process in multiple jurisdictions.

It is not unusual in the pharmaceutical industry for patents to be challenged. The Immunomodulators I European patent was opposed by an anonymous third party in September 2021. The European Patent Office's ("EPO") preliminary opinion on the opposition was received in March 2023, identifying a number of items to be discussed at a hearing set for November 2023. Based on specialist advice received, and the fact that the patent went through an extensive examination process prior to being granted by the EPO, Poolbeg continues to have full confidence in the validity and strength of the patent and will vigorously defend its intellectual property to the extent required.

POLB 002 was also granted a European patent in January 2022, and a US patent was granted in May 2022 for the identification of defective interfering ("DI") RNA-based influenza viruses for use against infection by influenza, that provides a drug candidate with both antiviral prophylactic and therapeutic applications.

Outlook and Summary

We made substantial advancements in 2022, hitting key milestones in our programmes; particularly with the completion of our POLB 001 human challenge trial as well as the validation of our world first AI drug discovery programme. Our intellectual property has also been further protected by securing a number of patents in multiple territories, while successful and strategic in-licensing has created opportunities in exciting new areas with significant addressable markets. Having achieved excellent data in our first clinical trial and with a strong business development focus and a well capitalised business, we are excited to enter this next stage of development as we seek to partner our first programme.

Jeremy Skillington, PhD
CEO

29 March 2023

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 identify and de-risk infectious and other prevalent disease products, and to develop these products to the point of out-licensing. 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	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. Finding and hiring any additional personnel and replacements could be a costly and time consuming process, particularly in the biotechnology/ pharmaceutical industry.	The Board believes that the senior management team is appropriately structured for Poolbeg's size and 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.
Competition Risk	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 license its products.	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.
Development Risk	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. 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.	Poolbeg's approach of smart trial design, use of cutting edge technology, and a focus on in-licensing products where we can quickly produce early human efficacy data helps to mitigate this risk.

Risk	Details	Mitigation
Regulatory Risk	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 out-license its product candidates. In addition, positive human efficacy data does not guarantee that a product will be out-licensed by Poolbeg.	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. The Board reviews the out-licensing potential of all products Poolbeg has brought into its pipeline and is confident that with positive human efficacy, a market exists to out-license its products.
Intellectual Property Risk	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. 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.	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.
Funding and Partnering Risk	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. 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.	Poolbeg will avoid expensive, later-stage trials by seeking early monetisation, through licensing or partnering, which it expects should generate quicker returns than the conventional biotech model. Using a capital-light approach, Poolbeg's clinical development strategy is to rapidly demonstrate clinical proof-of-mechanism and/or proof–of–concept. 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 are actively exploring routes for non-dilutive grant funding to support the development of its pipeline, having already secured its first non-dilutive grant funding in 2022.

STRATEGIC REPORT:
Principal Risks and Uncertainties continued

Risk	Details	Mitigation
Pandemic, macro-economic and geopolitical Risk	There is an ongoing risk to Poolbeg due to unexpected global events that may negatively impact its ability to operate. This includes the outbreak of future strains of SARS-CoV-2 or escalation of geopolitical events in Europe. 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.	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. The Board continue to monitor the impact of the COVID-19 pandemic on all aspects of the group; most notably the safety of our employees and the impact on the development of our pipeline. The ultimate impact of COVID-19 is regularly reviewed and our management team ensure that all operational and clinical plans are designed and reviewed with sufficient flexibility to allow for any future disruptions. 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.

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 1 and 9. 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 2022.

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 2 to 13 was approved by the Board on 29 March and signed on its behalf by:

Jeremy Skillington
CEO

CORPORATE GOVERNANCE:
Board of Directors

Cathal Friel, Chairman

Cathal Friel is a successful entrepreneur, whom started working at the age of 16 due to his father's untimely illness. He went on to complete his education by taking night classes, receiving an MBA from the University of Ulster in 1990. Cathal then spent the following five years lecturing International Marketing and Business Planning at the University of Ulster on a part-time basis while running his own technology services business. In 2001, Cathal was part of the team who successfully established Merrion Stockbrokers in Dublin and in 2007 he founded Raglan Capital.

Cathal is the Chairman and Co-Founder of hVIVO plc (formerly Open Orphan plc) which successfully IPO'd on the London and Dublin stock exchanges in June 2019. Prior to this in 2015, he co-founded Amryt Pharma plc, along with Joe Wiley, which listed on the London Stock Exchange in 2016 and which has been listed on Nasdaq since July 2020. Prior to Amryt, Cathal founded Fastnet Oil & Gas plc in 2011 which he IPO'd on the London Stock Exchange. Cathal was a finalist in the International category of the EY Entrepreneur of the Year 2020.

Jeremy Skillington, Chief Executive Officer

Jeremy Skillington 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 investment fund HS Lifesciences GmbH to provide start-up and business development support to portfolio companies ImmunoQure AG and Ethris GmbH.

Jeremy joined Inflazome on its founding in 2016 and was instrumental in their acquisition by Roche in September 2020 for €380M upfront and significant downstream milestones. Jeremy studied Biochemistry at the National University of Ireland, Galway where he was awarded his Ph.D. He performed his post-doctoral research at the University of California, San Francisco in the lab of Prof Rik Derynck.

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.

Patrick Ashe, Non-Executive Director

Patrick Ashe has a career spanning 30 years as a business executive and entrepreneur in the pharmaceutical and biotechnology industry. He spent 16 years with Elan Corporation plc and served as Vice President of Business Development in its US division from 1994 – 2001. He was subsequently a co-founder and led the business and corporate development functions of specialty pharma companies Athpharma (2001-2004) and AGI Therapeutics plc (2004 – 2011), and the orphan disease company Vidara Therapeutics (2011 – 2014).

Following the sale of Vidara to Horizon Therapeutics plc in 2014, Patrick became Senior Vice President of Business Development of Horizon, a role he held until his retirement in 2016. Patrick has served as a board director for a number of private and public companies. Patrick holds a BSc (Hon) in Pharmacology from University College Dublin and an MBA from Dublin City University Business School.

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 recently 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.

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.

The Board consists of the Chairman, two Executive Directors, and three Non-Executive Directors. The Company regards three of the Non-Executive Directors as "independent Non-Executive Director". The Board has determined that Patrick Ashe, 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. 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 Patrick Ashe as chairman with Cathal Friel and Eddie Gibson as the other members and meets at least twice a year. 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 Eddie Gibson as chairman with Patrick Ashe and Cathal Friel as the other members. 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	5/5	2/2	1/1
Eddie Gibson	5/5	2/2	1/1
Luke O'Neill	3/5	–	–
Total meetings held in the period	**5**	**2**	**1**

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 in infectious disease 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 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.

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 2022. The Company is registered in England and Wales with registered number 13279507.

Principal Activities

The principal activity of the Group is the development of innovative medicines to address the unmet need in infectious and other prevalent diseases. The Group simultaneously advances multiple programmes in cost-effective clinical trials, rapidly generating early human safety and efficacy data to enable early partnering / out-licensing to pharmaceutical and biotechnology companies.

CORPORATE GOVERNANCE:
Group Directors' Report
For the year ended 31 December 2022

Review of the Year
A summary of Poolbeg's business activities during the year is set out in:

- The Chairman's Statement on page 1
- The CEO's Operations Review on page 2

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 £2,204,000 (2021: £414,000) 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 30 to 36 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
Cathal Friel	Chairman
Jeremy Skillington	Chief Executive Officer
Ian O'Connell	Chief Financial Officer
Patrick Ashe	Non-Executive Director
Eddie Gibson	Non-Executive Director
Luke O'Neill	Non-Executive Director

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 2022 was as follows:

Director	Base Salary and Fees £'000	Bonuses £'000	Pension Contributions £'000	Other Benefits £'000	Other Fees £'000	**2022 Total £'000**	2021 Total £'000
Cathal Friel	100	38	–	–	–	**138**	79
Jeremy Skillington	250	31	25	4	–	**310**	261
Ian O'Connell	145	54	15	6	–	**220**	172
Patrick Ashe	35	–	–	–	–	**35**	18
Eddie Gibson	35	–	–	–	–	**35**	18
Luke O'Neill [A]	25	–	–	–	15	**40**	21
2022 TOTAL	**590**	**123**	**40**	**10**	**15**	**778**	**569**

[A] Other fees relate to his role on the Scientific Advisory Board

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 annual base salary and fees, which applied in 2022 and will apply in 2023, for Directors are set out below:

Director	Base Salary and Fees £'000
Cathal Friel	100
Jeremy Skillington	250
Ian O'Connell	145
Patrick Ashe [A]	35
Eddie Gibson [A]	35
Luke O'Neill [B]	40
TOTAL	**605**

[A] Includes a fee of £10,000 for being chair of a Board committee
[B] Includes a fee of £15,000 for his role on the Scientific Advisory Board

The Remuneration Committee, in discussion with the Executive Directors, review annual performance at the end of each calendar year. The Chairman, CEO and CFO may be eligible for annual bonuses of up to 50% of base salary, at the Company's absolute discretion.

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	31 December 2022 %	31 December 2022 Number	31 December 2021 Number
Cathal Friel	**7.28**	**36,389,757**	36,389,757
Jeremy Skillington	**0.14**	**718,733**	–
Ian O'Connell	**1.67**	**8,326,839**	8,326,839
Patrick Ashe	**0.05**	**263,147**	263,147
Eddie Gibson	**–**	**–**	–
Luke O'Neill	**–**	**–**	–

CORPORATE GOVERNANCE:
Group Directors' Report continued

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 2021 & 2022 Number	Exercise price	Grant Date	Expiry Date
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 [B]	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. The option holder must be employed by the Group on the 12 month anniversary of AIM admission and cannot have given or received notice of termination of employment on or before such date

[B] The closing share price must be at least £0.15 for five consecutive business days when exercised. The option holder must be employed by the Group on the 18 month anniversary of AIM admission and cannot have given or received notice of termination of employment on or before such date

[C] The closing share price must be at least £0.20 for five consecutive business days when exercised. The option holder must be employed by the Group on the 24 month anniversary of AIM admission and cannot have given or received notice of termination of employment on or before such date

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:

Rank	Investor	15 March 2023[A] Number	15 March 2023[A] %	31 December 2022 Number	31 December 2022 %
1	Cathal Friel	**36,389,757**	**7.28**	**36,389,757**	**7.28**
2	Schroders PLC	**24,994,777**	**4.99**	**25,641,941**	**5.13**
3	Michael Kelly	**18,168,127**	**3.63**	**–[B]**	**–[B]**

[A] Latest date for which information was available prior to signing the financial statements

[B] Below disclosure requirements

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

Whilst COVID-19, and the associated uncertainties are now receding, 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. Suppliers and key stakeholders have all made adjustments to minimise disruptions and to facilitate the continued efficient running of their businesses and the Company does not foresee any significant problems in relation to its operations in the coming year.

After making appropriate enquires, 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 enquires 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 2022.

The Board's strategy is to develop multiple products faster and more cost effectively than the conventional biotech model and to move to rapidly monetise its products to larger pharmaceutical and biotechnology companies. 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 severe influenza and as a CAR T cell companion 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 POLB 002 and POLB 003 in order to move them towards the clinic and additional spend on the asset pipeline including advancing the Group's AI data powered drug programmes following receipt of programme outputs in 2023. 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 2022.

Political Donations

The Group made no political donations during the year.

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.

Auditor

The Board are recommending Gravita Audit Limited (formerly Jeffreys Henry Audit Ltd) 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.

CORPORATE GOVERNANCE:
Group Directors' Report continued

Disclosure of Information to the Auditor

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 March 2023 and signed on its behalf by:

Cathal Friel
Chairman

FINANCIAL STATEMENTS
Independent Auditor's Report
For the year ended 31 December 2022

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

Opinion

We have audited the financial statements of Poolbeg Pharma Plc for the year ended 31 December 2022 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 financial statements is applicable law and UK adopted international accounting standards.

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 2022 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 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 proposed research and development and operating costs for a period of at least 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.

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.

FINANCIAL STATEMENTS
Independent Auditor's Report continued

Key audit matter	How our audit addressed the key audit matter
Intangible assets The carrying value of the Group's intellectual property assets as at 31 December 2022 amounted to £ 2,134,000 (2021: £1,563,000). The additions this year were £597,000 (2021: £1,581,000). 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. The Directors have assessed whether the costs meet the criteria for capitalisation and whether there are any indicators of impairment. 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. Profit after tax, which is considered by management to be a key metric, is directly impacted by the amount of costs capitalised.	We have performed the following audit procedures: • 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 addition capitalised to invoices, to confirm that they are correct capital item 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. 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.

Key audit matter	How our audit addressed the key audit matter
Carrying value of investments in subsidiaries and recoverability of intercompany loans – parent company financial statements only. The Company had investments of £2,169,000 (2021: £1,740,000) at the year ended 31 December 2022. The Directors have confirmed all investments, including additions were correctly calculated and being held at cost. The amounts due from subsidiaries amounts to £5,937,000. (2021: £1,520,000). We identified a risk that the investment held within the parent company financial statements in its subsidiaries and amounts receivable, may be impaired. 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.	We have performed the following audit procedures: • 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; • Reviewed the intangibles for any indication of impairment; • Assessed the appropriateness and applicability of 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. Based on the audit work performed, we are satisfied with management's assertion that no impairment exists.

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.

FINANCIAL STATEMENTS
Independent Auditor's Report continued

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	£220,000 (2021: £117,000)	£42,000 (2021: £35,000)
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.

We agreed with the Audit Committee that we would report to them misstatements identified during our audit for the Group above £11,000 (2021: £5,850) and for the Company above £2,100 (2021: £1,750) 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 (2021: 3 reporting units), comprising the Group's operating businesses and holding companies.

We performed audits of the complete financial information of Poolbeg Pharma Plc and 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.

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.

FINANCIAL STATEMENTS
Independent Auditor's Report continued

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 noncompliance 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.

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 March 2023

Consolidated Statement of Comprehensive Income

For the year ended 31 December 2022

	Note	Year to 31 December 2022 £'000	Period to 31 December 2021 £'000
Revenue		**–**	–
Cost of sales		**–**	–
Gross profit		**–**	–
Administrative expenses		**(3,060)**	(2,031)
Other operating income	3	**278**	109
Research and development expenses		**(2,204)**	(414)
Operating loss	4	**(4,986)**	(2,336)
Finance income		**209**	–
Loss before income tax		**(4,777)**	(2,336)
Taxation	6	**91**	–
Loss and total comprehensive loss for the period attributable to the equity holders of the Company		**(4,686)**	(2,336)
Loss per share:			
Loss per share – basic and diluted, attributable to ordinary equity holders of the parent (pence)	7	**(0.94)**	(0.74)

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 2022

	Note	31 December 2022 £'000	31 December 2021 £'000
Assets			
Non-current assets			
Intangible assets	8	**2,134**	1,563
Total non-current assets		**2,134**	1,563
Current assets			
Trade and other receivables	10	**962**	506
Cash and cash equivalents	11	**16,193**	20,949
Total current assets		**17,155**	21,455
Total assets		**19,289**	23,018
Equity and liabilities			
Equity attributable to owners of the parent			
Share capital	12	**100**	100
Share premium		**23,100**	23,100
Other reserves		**2,145**	1,716
Accumulated deficit		**(7,022)**	(2,336)
Total equity		**18,323**	22,580
Current liabilities			
Trade and other payables	14	**966**	438
Total current liabilities		**966**	438
Total liabilities		**966**	438
Total equity and liabilities		**19,289**	23,018

The Financial Statements set out on pages 30 to 52 were approved and authorised for issue by the Directors on 29 March 2023.

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 2022

	Note	Share capital £'000	Share premium £'000	Share based payment reserve £'000	Merger reserve £'000	Accumulated deficit £'000	Total £'000
Loss and total comprehensive loss for the period		–	–	–	–	(2,336)	**(2,336)**
Issue of shares as part of demerger		45	–	–	1,455	–	**1,500**
Issue of shares for cash		55	24,950	–	–	–	**25,005**
Costs charged against share premium		–	(1,829)	–	–	–	**(1,829)**
Share based payments	13	–	(21)	261	–	–	**240**
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**

Consolidated Statement of Cash Flows

For the year ended 31 December 2022

	Note	Year to 31 December 2022 £'000	Period to 31 December 2021 £'000
Cash flows from operating activities			
Loss on ordinary activities before taxation		**(4,777)**	(2,336)
Amortisation	8	**26**	18
Share based payment expense	13	**429**	240
Finance income		**(209)**	–
SME R&D tax credit	6	**91**	–
Movements in working capital and other adjustments:			
Change in trade and other receivables	10	**(456)**	(506)
Change in trade and other payables	14	**528**	438
Net cash flow used in operating activities		**(4,368)**	(2,146)
Cash flow from investing activities			
Payments for intangible assets	8	**(597)**	(81)
Interest received from bank		**209**	–
Net cash flow used in investing activities		**(388)**	(81)
Cash flow from financing activities			
Proceeds from issue of equity instruments - net of expenses		**–**	23,176
Short term loans received		**–**	225
Repayment of short term loans		**–**	(225)
Net cash flow from financing activities		**–**	23,176
Net change in cash and cash equivalents		**(4,756)**	20,949
Cash and cash equivalents at beginning of period		**20,949**	–
Cash and cash equivalents at end of period	11	**16,193**	20,949

Company Statement of Financial Position

As at 31 December 2022

	Notes	31 December 2022 £'000	31 December 2021 £'000
Assets			
Non-current assets			
Investment in subsidiaries	9	**2,169**	1,740
Loans to subsidiaries	9	**5,937**	1,520
Total non-current assets		**8,106**	3,260
Current assets			
Trade and other receivables	10	**301**	281
Cash and cash equivalents	11	**15,753**	20,774
Total current assets		**16,054**	21,055
Total assets		**24,160**	24,315
Equity and liabilities			
Equity attributable to owners of the company			
Share capital	12	**100**	100
Share premium		**23,100**	23,100
Other reserves		**2,145**	1,716
Accumulated deficit		**(1,341)**	(705)
Total equity		**24,004**	24,211
Current liabilities			
Trade and other payables	14	**156**	104
Total current liabilities		**156**	104
Total liabilities		**156**	104
Total equity and liabilities		**24,160**	24,315

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 £636,000 (2021: £705,000).

The Financial Statements set out on pages 30 to 52 were approved and authorised for issue by the Directors on 29 March 2023.

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 2022

	Note	Share capital £'000	Share premium £'000	Share based payment reserve £'000	Merger reserve £'000	Accumulated deficit £'000	Total £'000
Loss and total comprehensive loss for the period		–	–	–	–	(705)	**(705)**
Issue of shares as part of demerger		45	–	–	1,455	–	**1,500**
Issue of shares for cash		55	24,950	–	–	–	**25,005**
Costs charged against share premium		–	(1,829)	–	–	–	**(1,829)**
Share based payments		–	(21)	261	–	–	**240**
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**

Company Statement of Cash Flows

For the year ended 31 December 2022

	Notes	Year to 31 December 2022 £'000	Period to 31 December 2021 £'000
Cash flows from operating activities			
Loss for the period – continuing operations		**(636)**	(705)
Loss for the period		**(636)**	(705)
Finance income		**(432)**	(17)
Movements in working capital and other adjustments:			
Change in trade and other receivables	10	**(20)**	(281)
Change in trade and other payables	14	**52**	104
Net cash flow used in operating activities		**(1,036)**	(899)
Cash flow from investing activities			
Funds advanced to subsidiary companies		**(4,194)**	(1,503)
Interest received from bank		**209**	–
Net cash flow used in investing activities		**(3,985)**	(1,503)
Cash flow from financing activities			
Proceeds from issue of equity instruments - net of expenses		**–**	23,176
Net cash flow from financing activities		**–**	23,176
Net change in cash and cash equivalents		**(5,021)**	20,774
Cash and cash equivalents at beginning of period		**20,774**	–
Cash and cash equivalents at end of period	11	**15,753**	20,774

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 specialises in the development of innovative medicines to address the unmet need in infectious and other prevalent diseases. Poolbeg has a disciplined portfolio approach to mitigate risk, accelerate drug development and enhance investor returns.

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 2022. 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. The prior period merger reserve was created on the acquisition of ORPH Pharma IP Company Limited by Poolbeg Pharma plc (see note 12).

Comparative period

The comparative period is for the period from incorporation on 19 March 2021 to 31 December 2021.

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 £16.2m as at 31 December 2022 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 23 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.

Notes to the Financial Statements continued

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 2022	1.1702	1.2101
At 31 December 2022	1.1284	1.2329

(US$ = US Dollars; € = Euro)

Foreign currency units to 1 £	€	US$
Average period to 31 December 2021	1.1698	1.3728
At 31 December 2021	1.1898	1.3527

(US$ = US Dollars; € = Euro)

Accounting policies and disclosures

The accounting policies adopted are consistent throughout the financial period. Standards and amendments to IFRS effective as of 1 January 2022 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 2022 but were not effective at 31 December 2022 and have not been adopted for these Financial Statements. These include:

- Amendments to IFRS 16 Leases – requirements on accounting for sale and leaseback after the date of transaction (applicable on or after 1 January 2024)
- IFRS 17 Insurance Contracts – applicable on or after 1 January 2023
- Amendments to IAS 1 Presentation of Financial Statements – further disclosure requirements including additional detail around accounting policies (applicable on or after 1 January 2023)
- Amendments to IAS 8 Accounting Policies, Changes in Accounting Estimates and Errors – definition of accounting estimates (applicable on or after 1 January 2023)

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 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.

(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. As the Group has not yet 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 not been recognised in the Income Statement.

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;
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 £2,204,000 (2021: £414,000) 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.

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.

Notes to the Financial Statements continued

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.

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 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.

Where eligible the Group applies for R&D tax credits in the jurisdictions in which it operates. As the Group has not yet 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 not been recognised in the Income Statement. The tax credit of £91,000 in the current year relates to the receipt of a SME R&D tax credit for a return submitted for the 2021 tax year. This is the first R&D tax credit received by the Group.

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.

Notes to the Financial Statements continued

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 period. Other operating income of £278,000 (2021: £109,000) is 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

	31 December 2022 £'000	31 December 2021 £'000
UK	**1,862**	1,563
Other countries	**272**	–
Total non-current assets	**2,134**	1,563

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

	Year to 31 December 2022 £'000	Period to 31 December 2021 £'000
Operating loss is stated after charging:		
Fees payable to the Company's auditor for audit of the Company's annual accounts	**20**	20
Fees payable to the Company's auditor and its associates for other services:		
The audit of the Company's subsidiaries pursuant to legislation	**4**	4
Tax compliance services	**–**	2
Assurance services on corporate finance transactions	**–**	30
Tax services on corporate finance transactions	**–**	13
Amortisation of intangible assets	**26**	18
Foreign exchange losses	**33**	67

5 Employees

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

Group	**Year to 31 December 2022 £'000**	Period to 31 December 2021 £'000
Directors	**6**	5
Research and development	**2**	–
Administrative	**4**	2
	12	7

Aggregate remuneration comprised:

	Group Year to 31 December 2022 £'000	Group Period to 31 December 2021 £'000	**Company Year to 31 December 2022 £'000**	Company Period to 31 December 2021 £'000
Wages and salaries	**1,313**	714	**278**	121
Social security costs	**134**	69	**17**	2
Pension costs	**69**	33	**5**	2
Other benefits	**13**	4	**–**	—
Share based payments – directors	**429**	247	**–**	7
Total employee costs	**1,958**	**1,067**	**300**	**132**

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 2022:

Director	Base Salary and Fees £'000	Bonuses £'000	Pension Contributions £'000	Other Benefits £'000	**2022 Total £'000**	2021 Total £'000
Jeremy Skillington	250	31	25	4	**310**	261

In addition, share options were granted during the prior period (see the Group Directors' Report for details).

6 Taxation

The current year tax credit is made up as follows:

	Year to 31 December 2022 £'000	Period to 31 December 2021 £'000
Current tax:		
Corporation tax on losses for the period	**–**	–
Prior period adjustment in respect of research and development tax credit	**(91)**	–
Tax credit in Income Statement	**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:

	Year to 31 December 2022 £'000	Period to 31 December 2021 £'000
Loss before tax	**(4,777)**	(2,336)
Tax credit at normal rate of UK corporation tax of 19%	**(908)**	(444)
Effect of:		
Prior period adjustments	**(91)**	–
Losses unutilised	**744**	346
Expenses not deductible for tax purposes	**52**	46
Differences in overseas taxation rates	**112**	52
Current tax credit for the period	**(91)**	–

Notes to the Financial Statements continued

The Group has tax losses of up to £4,472,000 (2021: £2,095,000) to carry forward against future profits. The deferred tax asset on tax losses at 25% of £1,118,000 (2021: £398,000 at 19%) 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 130% 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% 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

Share Issue Details	Number of shares	Weighted average shares
19 March 2021 - Issue of shares on incorporation	5,000 [A]	
20 May 2021 - Issue of shares – share placing	24,992,500	
18 June 2021 - Issue of shares on acquisition of ORPH Pharma IP Company Limited	225,002,500	
16 July 2021 - Issue of shares – EIS/VCT	23,010,000	
19 July 2021 - Issue of shares – share placing on IPO	226,990,000	
31 December 2021	500,000,000	317,227,413
31 December 2022	**500,000,000**	**500,000,000**

[A] On 20 May 2021 the one ordinary share of £1 issued on incorporation of the Company was subdivided into 5,000 ordinary shares of 0.02p each

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

	Year to 31 December 2022	Period to 31 December 2021
Loss after tax attributable to equity holders of the Company (£'000)	**(4,686)**	(2,336)
Weighted average number of ordinary shares in issue	**500,000,000**	317,227,413
Fully diluted average number of ordinary shares in issue	**500,000,000**	317,227,413
Basic and diluted loss per share (pence)	**(0.94)**	(0.74)

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 2022 totalled 36,829,181 (2021: 36,829,181) and are potentially dilutive.

8 Intangible Assets

Group	Acquired Licences & Data £'000	Patents & Trademarks £'000	Total £'000
Cost			
Additions	1,500	81	1,581
At 31 December 2021	1,500	81	1,581
Additions	435	162	597
At 31 December 2022	**1,935**	**243**	**2,178**
Accumulated amortisation			
Amortisation charge	18	–	18
At 31 December 2021	18	–	18
Amortisation charge	25	1	26
At 31 December 2022	**43**	**1**	**44**
Net book value			
Net book value at 31 December 2022	**1,892**	**242**	**2,134**
Net book value at 31 December 2021	1,482	81	1,563

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. During the year the Group did not identify any potential changes in the assumptions used in the assessment of the carrying value of the assets.

9 Investment in subsidiaries

Company	Equity in subsidiary companies £'000	Subsidiary funding £'000	Total £'000
Cost			
Additions	1,740	1,520	3,260
At 31 December 2021	1,740	1,520	3,260
Additions	429	4,417	4,846
At 31 December 2022	**2,169**	**5,937**	**8,106**
Impairment			
Balance at 31 December 2021	–	–	–
Balance at 31 December 2022	**–**	**–**	**–**
Net book value			
At 31 December 2022	**2,169**	**5,937**	**8,106**
At 31 December 2021	1,740	1,520	3,260

The current year additions include share-based payment charges of £429,000 (2021: £240,000) for share options granted to employees of subsidiary companies.

Notes to the Financial Statements continued

Funding additions relate to the advancement of loans to 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	**2022 % holding**	2021 % holding
Poolbeg Pharma (Ireland) Limited	Pharmaceuticals R&D and management services	698030	Ireland	**100**	100
ORPH Pharma IP Company Limited	Pharmaceuticals R&D	13279216	UK	**100**	100
OP Holdco 2021 Limited	Dormant	13356328	UK	**100**	–

OP Holdco 2021 Limited was acquired on 30 May 2022. The company had no activities during the year.

List of registered offices:

Company	Registered Office Address
Poolbeg Pharma (Ireland) Limited	4th Floor, Fitzwilliam Hall, Fitzwilliam Place, Dublin 2, D02 T292, Ireland
ORPH Pharma IP Company 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 31 December 2022 £'000	Group 31 December 2021 £'000	**Company 31 December 2022 £'000**	Company 31 December 2021 £'000
Trade receivables	–	8	–	8
Prepayments and accrued income	**878**	449	**274**	256
VAT recoverable	**84**	49	**27**	17
Trade and other receivables	**962**	506	**301**	281

11 Cash and cash equivalents

	Group 31 December 2022 £'000	Group 31 December 2021 £'000	**Company 31 December 2022 £'000**	Company 31 December 2021 £'000
Bank current accounts	**1,069**	20,949	**629**	20,774
Short term notice deposits	**15,124**	–	**15,124**	–
Total Cash and cash equivalents	**16,193**	20,949	**15,753**	20,774

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
Issued during 2021	500,000,000	100
At 31 December 2021	500,000,000	100
At 31 December 2022	**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 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.

Share options and warrants in issue:

	Share Options		Warrants	
	Units	Weighted average exercise price	Units	Weighted average exercise price
Granted during 2021	36,000,000	13.3p	829,181	10.0p
Balance at 31 December 2021 & 31 December 2022	**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.

The fair value is estimated at the date of grant using the Black-Scholes pricing model, taking into account the terms and conditions attached to the grant. The following are the inputs to the model for the equity instruments granted during the prior period:

	2021 Options Inputs	2021 Warrants Inputs
Expected life	4 years	3-4 years
Expected volatility	52%	52%
Risk-free interest rate	0.31%	0.31%
Share price at grant	10p	10p
Fair value per award	1.2p-2.8p	2.5p-2.8p

During the prior period 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 2022 have a weighted remaining contractual life of 8.5 years with exercise prices ranging from £0.10 to £0.15.

During the prior period, a total of 829,181 warrants exercisable at a weighted average price of £0.10 were granted. The warrants outstanding as at 31 December 2022 have a weighted remaining contractual life of 3.6 years with an exercise price of £0.10.

Notes to the Financial Statements continued

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

	Year to 31 December 2022 £'000	Period to 31 December 2021 £'000
Share options	**429**	240
Total	**429**	240

14 Trade and other payables

	Group 31 December 2022 £'000	Group 31 December 2021 £'000	Company 31 December 2022 £'000	Company 31 December 2021 £'000
Trade payables	**293**	79	**35**	6
Accrued expenses	**623**	309	**115**	84
Other payables	**4**	3	**2**	2
Social security costs and other taxes	**46**	47	**4**	12
Trade and other payables	**966**	438	**156**	104

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:

Directors	Group Year to 31 December 2022 £'000	Group Period to 31 December 2021 £'000	Company Year to 31 December 2022 £'000	Company Period to 31 December 2021 £'000
Directors' remuneration (short term benefits)	**723**	538	**170**	82
Directors' remuneration (pension cost)	**40**	23	**–**	–
Share based payments	**429**	247	**–**	7
Other fees	**15**	8	**15**	8
Total	**1,207**	816	**185**	97

Shares purchased by Directors

During the year the Directors of the Company purchased ordinary shares of 0.02p as follows:

Director	Number
Jeremy Skillington	718,733
Total	**718,733**

Other transactions with Directors

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

Directors	**Group Year to 31 December 2022 £'000**	Group Period to 31 December 2021 £'000	**Company Year to 31 December 2022 £'000**	Company Period to 31 December 2021 £'000
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.

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:

Subsidiary company	**31 December 2022 £'000**	31 December 2021 £'000
ORPH Pharma IP Company Limited	**3,493**	649
Poolbeg Pharma (Ireland) Limited	**2,444**	871
Total	**5,937**	1,520

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

Subsidiary company	**Year to 31 December 2022 £'000**	Period to 31 December 2021 £'000
ORPH Pharma IP Company Limited	**123**	8
Poolbeg Pharma (Ireland) Limited	**100**	9
Total	**223**	17

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

Subsidiary company	**Year to 31 December 2022 £'000**	Period to 31 December 2021 £'000
ORPH Pharma IP Company Limited	**72**	56

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:

Subsidiary company	**Year to 31 December 2022 £'000**	Period to 31 December 2021 £'000
ORPH Pharma IP Company Limited	**25**	25

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

Notes to the Financial Statements continued

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 Year to 31 December 2022 £'000	Group Period to 31 December 2021 £'000	Company Year to 31 December 2022 £'000	Company Period to 31 December 2021 £'000
Financial assets (all at amortised cost):				
Cash and cash equivalents	**16,193**	20,949	**15,753**	20,774
Trade and other receivables (excluding prepayments)	**144**	85	**87**	65
Total financial assets	**16,337**	21,034	**15,840**	20,839
Financial liabilities:				
At amortised cost				
Trade and other payables	**966**	438	**156**	104
Total financial liabilities	**966**	438	**156**	104
Net	**15,371**	20,596	**15,684**	20,735

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:

31 December 2022	**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**
Current liabilities	539	318	109	–	**966**

31 December 2021	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
Current liabilities	217	213	6	2	438

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

31 December 2022	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
Current liabilities	75	32	49	–	**156**

31 December 2021	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
Current liabilities	64	39	1	–	104

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 £186,000.

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 £18,000 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.

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.

Notes to the Financial Statements continued

18 Events after the reporting period

Poolbeg's Immunomodulators I European patent (EP3478322) was opposed by an anonymous third party in September 2021. In March 2023, Poolbeg received the preliminary opinion on the opposition from The European Patent Office's ("EPO"), which identified a number of items to be discussed at a hearing set for November 2023. Based on specialist advice received, and the fact that the patent went through an extensive examination process prior to being granted by the EPO, Poolbeg continues to have full confidence in the validity and strength of the patent and will vigorously defend its intellectual property to the extent required.

In January 2023 & March 2023, Poolbeg announced positive results from the POLB 001 LPS Human Challenge Trial. Treatment with POLB 001 resulted in a highly significant reduction in p38 MAP kinase driven cytokines and exhibited a marked reduction in multiple markers of systemic and local inflammation compared with placebo. The trial results demonstrate expected utility in severe influenza.

In January 2023, Poolbeg announced the strategic expansion of POLB 001 into oncology and the filing of a patent application to protect use of POLB 001 for new oncology indication. Scientific findings indicate POLB 001 has the potential to dampen the pro-inflammatory cytokine release syndrome affecting patients receiving CAR T cell therapies.

In March 2023, Poolbeg announced that an additional POLB 001 was granted in by the US Patent and Trademark Office, for use of certain p38 MAP kinase inhibitors for treatment of hypercytokinemia.

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