RNS Number : 6890U
Poolbeg Pharma PLC
30 March 2023

Poolbeg Pharma Plc

Results for the year ended 31 December 2022

Significant milestones reached, well capitalised and positioned for future growth

London, UK 30 March 2023 - Poolbeg Pharma Plc (AIM: POLB, OTCQB: POLBF "Poolbeg" or the "Company") leading biopharmaceutical company focusing on infectious and prevalent diseases with a high unmet medical need, is pleased to announce its audited results for the year ended 31 December 2022.

Financial & Corporate Highlights

- Well capitalised with a cash balance of £16.2m at year end
- Poolbeg-led consortium awarded €2.3m in non-dilutive funding to progress its Oral Vaccine Platform
- Select experienced hires, bolstering the Company's capabilities in core areas such as business development and clinical operations

Operational Highlights

- ***POLB 001*** - potential blockbuster p38 MAP Kinase inhibitor for the treatment of severe Influenza and other acute inflammatory conditions
  - Successfully completed the bacterial lipopolysaccharide ("LPS") human challenge trial in 2022
  - Positive results from the trial were published earlier this month. POLB 001 was shown to be safe and well tolerated and had a potent effect on systemic and localised inflammatory response in a dose dependent manner. This significant milestone demonstrates POLB 001's expected utility in severe influenza and supports its continued development in other acute inflammatory conditions
  - Poolbeg continues 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

- ***POLB 001 - Oncology***
  - Strategically expanded POLB 001 in January 2023 as a potential treatment option for Cytokine Release Syndrome (CRS), a side-effect associated with CAR T cell therapy. Clinical trial enabling activities are underway with trial initiation in CAR T cell patients expected in H1 2024

- ***Artificial Intelligence ("AI") Programmes***- analysis of unique disease progression data derived from human challenge trial samples
  - **Respiratory Syncytial Virus ("RSV") AI programme**with partner OneThree Biotech. Poolbeg embarked on a world first programme in February 2022 which yielded multiple novel RSV drug targets in November 2022. Following the discovery of these drug targets, the collaboration successfully identified a number of promising RSV drug candidates which can now be rapidly brought forward to lab-based validation
  - **Influenza AI programme**with leading AI company, CytoReason, commenced in March 2022 and hit a major milestone in November 2022 as the construction of the computational artificial intelligence influenza disease model was completed

- ***Continued expansion and diversification of the pipeline***
  - **POLB 002**- in-licensed an intra-nasally administered, RNA-based immunotherapy for pan-respiratory virus infections
  - **POLB 003** - in-licensed late-preclinical stage intra-muscular vaccine candidate for the prevention of Melioidosis, a predominantly tropical / subtropical disease with a high mortality rate and no approved vaccine available
  - The Company continues to evaluate five other bacterial vaccine candidates being developed at University College Dublin ("UCD") under an ongoing option agreement

- **Oral Vaccine Platform** - licensed microencapsulation and nanoencapsulation technology aimed at triggering 'mucosal immunity' by delivering oral vaccines to the gut, preventing infections from taking hold in the body by counteracting them at the point of entry, both reducing transmission and preventing serious disease
- **Oral Delivery of Metabolic Disease Treatments**- licensed patented encapsulation technologies in metabolic syndrome related diseases, including obesity, pre-diabetes and diabetes

Jeremy Skillington, PhD, Chief Executive Officer, Poolbeg Pharma, said: *"As we reflect on Poolbeg's accomplishments in 2022, we are delighted with the progress we have made in our pipeline development, clinical programmes, and our AI drug discovery programmes. Our strong cash position, coupled with the excellent data achieved in our LPS human challenge trial for POLB 001, position us well for 2023 as we work towards our first partnering transaction. We remain committed to disciplined capital allocation, cost-effective R&D, and strategic partnerships, as we continue to pursue our goal of becoming a one-stop-shop for pharma and biotechs seeking products to in-license."*

Investor presentation

The Company will provide a live presentation relating to the results for the year ended 31 December 2022 via the Investor Meet Company platform on Thursday 30 March 2023 at 10:00 BST.

The presentation is open to analysts and all existing and potential shareholders. Investors can sign up to Investor Meet Company for free and add to meet Poolbeg Pharma here. Those who already follow Poolbeg Pharma on the Investor Meet Company platform will automatically be invited.

The Company's Annual Report and Accounts for the year ended 31 December 2022 will be posted to shareholders in due course together with the notice of the 2023 Annual General Meeting, and will be available on the Company's website: www.poolbegpharma.com/investors/documents/

- Ends -

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About Poolbeg Pharma

Poolbeg Pharma 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. The Company simultaneously advances multiple programmes in cost-effective clinical trials, rapidly generating early human safety and efficacy data to enable early partnering / out-licensing, with the funds generated reinvested in the pipeline. Poolbeg also uses AI to interrogate human challenge trial data sets to quickly identify new targets and drugs, and in-license near or in the clinic medicines, leading to faster development and greater commercial appeal.

The Company is targeting the growing infectious disease market. In the wake of the COVID-19 pandemic, infectious disease has become one of the fastest growing pharma markets and is expected to exceed $250bn by 2025. Through opportunistic identification of assets which complement Poolbeg's existing pipeline, the Company is progressing programmes in oncology and metabolic syndromes; adding disease areas with significant addressable markets.

With its initial assets from hVIVO plc (formerly Open Orphan plc),an industry leading infectious disease and human challenge trials business, Poolbeg has access to knowledge, experience, and clinical data from over 20 years of human challenge trials. The Company is using these insights to acquire new assets as well as reposition clinical stage products,

reducing spend and risk. Amongst its portfolio of exciting assets, Poolbeg has a small molecule immunomodulator for severe influenza and other acute inflammatory conditions (POLB 001) which produces a highly significant reduction in p38 MAP kinase driven cytokines in a clinical setting; a first-in-class, intranasally administered RNA-based immunotherapy for respiratory virus infections (POLB 002); and a vaccine candidate for Melioidosis (POLB 003). The Company is also developing two Oral Delivery Programmes and is progressing two Artificial Intelligence (AI) Programmes to add promising new assets to its pipeline.

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

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 (anRNA-based immunotherapy for respiratory virus infections), POLB 003 (an intramuscular vaccine candidate to prevent Melioidosis), and for use of AnaBio Technologies's ("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 at year end. The loss for the year amounted to £4.7m and comprises R&D expenses £2.2m, administrative expenses £3.1m and other income and tax rebates of £0.6m. 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 biotechs seeking programmes to in-license. We look forward to continued progress in 2023.

Cathal Friel
Chairman
29 March 2023

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, 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.

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.

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 - 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 diseases 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 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 South- East 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.

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.

an industry that will be worth an estimated $[illegible]bn by 2031.

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.

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.

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 include 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

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		**278**	109
Research and development expenses		**(2,204)**	(414)
Operating loss		**(4,986)**	(2,336)
Finance income		**209**	-
Loss before income tax		**(4,777)**	(2,336)
Taxation		**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)	**3**	**(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	**4**	**2,134**	1,563
Total non-current assets		**2,134**	1,563
Current assets			
Trade and other receivables		**962**	506
Cash and cash equivalents		**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		**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		**966**	438
Total current liabilities		**966**	438
Total liabilities		**966**	438
Total equity and liabilities		**19,289**	23,018

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
Loss and total comprehensive loss for the period		-	-	-	-	(2,336)
Issue of shares as part of demerger		45	-	-	1,455	-
Issue of shares for cash		55	24,950	-	-	-
Costs charged against share premium		-	(1,829)	-	-	-
Share based payments		-	(21)	261	-	-
Balance at 31 December 2021		100	23,100	261	1,455	(2,336)
Loss and total comprehensive loss for the year		-	-	-	-	(4,686)
Share based payments		-	-	429	-	-
Balance at 31 December 2022		100	23,100	690	1,455	(7,022)

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	**4**	**26**	18
Share based payment expense		**429**	240
Finance income		**(209)**	**-**
SME R&D tax credit	**2**	**91**	**-**
Movements in working capital and other adjustments:			

Movements in working capital and other adjustments:			
Change in trade and other receivables		**(456)**	(506)
Change in trade and other payables		**528**	438
Net cash flow used in operating activities		**(4,368)**	(2,146)
Cash flow from investing activities			
Payments for intangible assets	**4**	**(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		**16,193**	20,949

Notes

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. 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.

Comparative period

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

Presentation of balances

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

Summary of significant accounting policies

Research and development expenses

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.

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.

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.

3. Loss per share - basic and diluted

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

Issued share capital - ordinary shares of 0.02p each

Share Issue Details	Number of shares	Weighted average shares
10 March 2021 - Issue of shares on incorporation	5,000 [A]	

19 March 2021 - Issue of shares on incorporation	5,000	
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.

4. 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.

5. 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.

6. Annual Report and Annual General Meeting

The Company's Annual Report and Accounts for the year ended 31 December 2022 will be posted to shareholders in due course together with the notice of the 2023 Annual General Meeting, and will be available on the Company's website, www.poolbegpharma.com/investors/documents/

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