Poolbeg Pharma plc

Interim results for the six months to 30 June 2023

Significant progress made and well positioned for future growth

13 September 2023 - Poolbeg Pharma (AIM: POLB, OTCQB: POLBF, 'Poolbeg' or the 'Company'), a clinical-stage biopharmaceutical company targeting diseases with a high unmet medical need, announces its unaudited interim results for the six months to 30 June 2023.

Interim Results Highlights and Business Update

- Strong cash balance of £14.1 million as at 30 June 2023 (31 December 2022: £16.2m)
- Positive results from the POLB 001 LPS human challenge trial. The asset has the potential to be an effective treatment for severe influenza and potentially other acute inflammatory conditions
- Strategic expansion of POLB 001 into oncology, including as a potential treatment option for Cytokine Release Syndrome (CRS), a side-effect associated with up to 95% of CAR T cell therapies
- Further to discussions with prospective partners interested in this area, the Company is actively exploring a potential new indication for POLB 001 in oncology beyond CAR T
- The Company's artificial intelligence (AI) programme with CytoReason provided unparalleled insights into influenza infection and successfully identified a number of novel and valuable drug targets
- The lab-based validation of the Respiratory Syncytial Virus (RSV) drug targets and treatments identified from the Company's AI-led programme is progressing and expected to complete in H2 2023
- The Poolbeg-led Oral Vaccine consortium (EncOVac), which was awarded €2.3 million in grant funding, progressed to the next phase of development, marked by the commencement of the encapsulation validation process
- Continued progress on the Oral GLP-1 agonist proof-of-technology clinical trial preparation. As a result of adopting recommendations from a number of Key Opinion Leaders (KOLs), the clinical trial design has been refined and the trial is expected to commence in H1 2024
- Industry veteran, Professor Brendan Buckley, appointed as Non-Executive Director in May 2023

Jeremy Skillington, PhD, Chief Executive Officer of Poolbeg Pharma, commented: *"During H1 2023, we made significant progress in advancing our pipeline, bolstered by the strong clinical trial data for POLB 001 and breakthroughs in our AI-led drug discovery programmes, we are building towards becoming an efficient one-stop-shop for biopharma seeking products to in-license. With a cost-effective R&D approach, complemented by a strong balance sheet and multiple non-dilutive funding opportunities, we are well positioned for ongoing development and future growth with a strong focus on our business development activities."*

Investor presentation

Jeremy Skillington, PhD, Chief Executive Officer, will be presenting at the Master Investor Sector Focus: Healthcare Webinar on **20 September 2023.**

Register to attend here.

Change of Name of Nominated Adviser and Joint Broker

The Company also announces that its Nominated Adviser and Joint Broker has changed its name to Cavendish Capital Markets Ltd following completion of its own corporate merger.

- 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 Pharma 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 Pharma also uses AI to interrogate human challenge trial data sets to quickly identify new targets and drugs, 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 Pharma'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, an industry leading infectious disease and human challenge trials business, Poolbeg Pharma 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 Pharma 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 progressing two Artificial Intelligence (AI) Programmes to add promising new assets to its pipeline as well as developing an Oral Vaccine Programme and an Oral Delivery Programme focussing on metabolic syndrome related diseases.

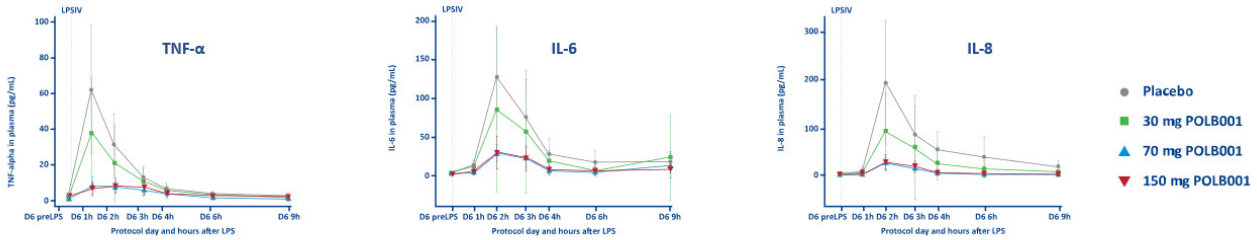
For more information, please go to www.poolbegpharma.com or follow us on Twitter and LinkedIn @PoolbegPharma.

CEO Statement

I am delighted to present the unaudited interim financial statements of Poolbeg Pharma plc ("Poolbeg" or the "Company") for the six months to 30 June 2023. Throughout this period, we've achieved substantial advancements across our programmes as outlined below.

Significant progress made

POLB 001 – Severe Influenza – We reported the positive results from our LPS human challenge trial for POLB 001 in March 2023 (see Figure 1) and the Clinical Study Report has been finalised. These findings demonstrated a significant reduction in both systemic and localised inflammatory responses in a manner that suggests expected utility in treating life-threatening infections, such as severe influenza, and supports continued development as a treatment for the Cytokine Release Syndrome ("CRS") associated with other acute inflammatory conditions.



TNF-α reduction of **73.5% and 56.2%** seen for **70 mg and 150 mg doses respectively** (p = 0.0003†)

IL-6 reduction of **57.4% and 63.5%** seen for **70 mg and 150 mg doses respectively** (p = 0.0002†)

IL-8 reduction of **80.7% and 76.7%** seen for **70 mg and 150 mg doses respectively** (p < 0.0001†)

TNF-α, IL-6 and IL-8 levels decreased between 56-81% in subjects treated with 70 mg or 150 mg POLB 001

Figure 1

POLB 001 – Oncology – Expanding the potential of POLB 001 beyond severe influenza remains a key objective for the Company to fully unlock the potential value of the molecule and strengthen Poolbeg's position for partnering and out-licensing. In line with this objective, we strategically expanded POLB 001 into oncology in January 2023 with the filing of a patent application for the use of POLB 001 as a treatment option for the Cytokine Release Syndrome (CRS) side-effect associated with CAR T cell therapy. CRS affects up to 95% of cancer patients receiving CAR T cell therapy, which, in its severe form, can be life threatening.

A potential new indication in oncology beyond CAR T is being actively explored further to discussions with prospective partners with interest in this area.

Clinical trial enabling activities to advance POLB 001 in oncology are progressing.

Influenza Artificial Intelligence Programme – In June 2023, our AI-led programme with CytoReason yielded a significant breakthrough. The programme identified multiple novel influenza drug targets by leveraging our unique disease progression data from human challenge trials combined with CytoReason's curated disease data and advanced AI platform. The insights gained offer an unparalleled understanding of influenza infection, focusing on the body's immune responses by identifying the drivers of disease, and identified multiple unique drug targets that hold the potential to block disease and aid recovery. The Company is actively exploring the most effective way to further develop the novel drug targets in order to generate value and is progressing towards drug target validation which is expected to complete in 2024.

RSV Artificial Intelligence Programme – In Q4 2022, the Company announced the successful identification of novel drug targets and treatments by our AI partner, OneThree Biotech. This significant breakthrough demonstrated the power of AI in accelerating drug discovery and identification and reaffirmed our confidence in the value of our data and our technology driven programmes. The lab-based validation of these treatments is expected to complete in H2 2023.

Oral Vaccine Programme – The Poolbeg-led Oral Vaccine consortium (EncOVac), which was awarded €2.3 million in grant funding, advanced into its next phase of development as the validation of the encapsulation process commenced in June 2023. The research plan, Consortium and Grant agreements have been completed and the programme is

progressing well with validation expected to complete in H2 2023. This programme holds the potential to address a wide range of infectious diseases, contributing positively to global health.

Oral Delivery of Metabolic Disease Treatments – The Company continues to make progress on the Oral GLP-1 agonist proof-of-technology clinical trial preparation. We actively engaged with a number of KOLs to refine the clinical trial design and, as a result of adopting these recommendations, the trial is now expected to commence in H1 2024. The trial aims to determine that a Glucagon-like Peptide 1 receptor ("GLP-1") agonist can be successfully delivered orally in humans using our licensed technology. GLP-1 agonists such as Wegovy® (semaglutide) are used to treat obesity and diabetes, and this trial has the potential to tap into an industry that will be worth an estimated $150 billion by 2031[1].

Other Updates – The Company continues to review partnering opportunities as well as actively exploring further non-dilutive funding opportunities to progress its programmes, including POLB 002 and POLB 003. The Company has taken another proactive step in enhancing its robust intellectual property by submitting a patent application for POLB 003 in the first half of this year.

As announced in March 2023, we successfully strengthened the patent portfolio of POLB 001 with another patent grant in the US, covering the use of certain p38 MAP kinase inhibitors for the treatment of hypercytokinaemia. Further to this, in January 2023 we filed patent applications for the use of POLB 001 in addressing the impact of CRS associated with CAR T cell therapy, as well as other oncology indications beyond CAR T. 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.

Business Development – We continue to evaluate partnering opportunities for a number of our programmes in line with our operating model. With more than 50% of late-stage programmes originating from partnering within the pharmaceutical industry, there is significant scope to aid companies in their mission to accelerate the development of unique medicines that address diseases with high unmet medical need.

We have seen great progress in a number of our programmes since the start of 2023, including the positive data from our POLB 001 LPS human challenge trial, completion of the Clinical Study Report, the strategic expansion of POLB 001 into oncology, and the discovery of multiple novel drug targets and treatments using AI. We have attended several global partnering conferences so far in 2023 which have facilitated further engagement with potential partners. With excellent relationships across the sector, and the positive outputs to hand from a number of our programmes, we look forward to continuing deal making discussions and providing updates to our shareholders in due course.

Corporate & Financial

Poolbeg had a strong cash balance of £14.1m as at 30 June 2023. Loss for the period amounted to £1.8m; comprised of R&D expenses of £0.9m, administrative expenses of £1.4m and other income of £0.5m.

We welcomed Professor Brendan Buckley to the Board as Non-Executive Director in May 2023. Brendan's significant contributions to Poolbeg as a member of the Scientific Advisory Board, and his extensive industry experience, greatly benefits the Company.

Outlook

Poolbeg has continued to make significant strides in progressing our pipeline of products and platforms during H1 2023 and we are continuing at pace towards our aim of becoming a one-stop-shop for pharma and biotech's seeking programmes to in-license. With strong data from our POLB 001 clinical trial and novel drug targets and treatments identified using our cutting-edge AI-led programmes, we are excited by the future of Poolbeg. Our robust cash balance, cost effective R&D approach, and multiple near term value inflection points position Poolbeg to generate strong returns for shareholders over the coming years.

[1] The Economist, 2023

Jeremy Skillington, PhD
Chief Executive Officer
12 September 2023

Consolidated Statement of Comprehensive Income
For the six months to 30 June 2023

	Note	**Unaudited Six months to 30 June 2023**	Unaudited Six months to 30 June 2022	Audited Year ended 31 December 2022
		£'000	£'000	£'000
Revenue		**—**	—	—
Cost of sales		**—**	—	—
Gross profit		**—**	—	—
Administrative expenses		**(1,395)**	(1,228)	(3,060)
Other operating income		**177**	133	278
Research and development expenses		**(865)**	(657)	(2,204)
Operating loss		**(2,083)**	(1,752)	(4,986)
Finance income		**272**	45	209
Loss before income taxation		**(1,811)**	(1,707)	(4,777)
Taxation	2	**—**	100	91
Loss and total comprehensive loss for the period attributable to the equity holders of the Company		**(1,811)**	(1,607)	(4,686)
Loss per share:				
Loss per share – basic and diluted, attributable to ordinary equity holders of the parent (pence)	3	**(0.36)**	(0.32)	(0.94)

Consolidated Statement of Financial Position

As at 30 June 2023

	Note	**Unaudited 30 June 2023 £'000**	Unaudited 30 June 2022 £'000	Audited 31 December 2022 £'000
Assets				
Non-current assets				
Intangible assets	4	**2,183**	1,935	2,134
Total non-current assets		**2,183**	1,935	2,134
Current assets				
Trade and other receivables	5	**767**	1,185	962
Cash and cash equivalents		**14,120**	18,894	16,193
Total current assets		**14,887**	20,079	17,155
Total assets		**17,070**	22,014	19,289
Equity and liabilities				
Equity attributable to owners of the parent				
Share capital		**100**	100	100
Share premium		**23,100**	23,100	23,100
Other reserves		**2,192**	1,930	2,145
Accumulated deficit		**(8,833)**	(3,943)	(7,022)
Total equity		**16,559**	21,187	18,323
Current liabilities				
Trade and other payables	6	**511**	827	966
Total current liabilities		**511**	827	966
Total liabilities		**511**	827	966
Total equity and liabilities		**17,070**	22,014	19,289

Consolidated Statement of Changes in Equity
For the six months to 30 June 2023

	Share capital £'000	Share premium £'000	Share based payment reserve £'000	Merger reserve £'000	Accumulated deficit £'000	Total £'000
At 1 January 2022	100	23,100	261	1,455	(2,336)	**22,580**
Loss and total comprehensive loss for the period	—	—	—	—	(1,607)	**(1,607)**
Share based payments	—	—	214	—	—	**214**
Balance at 30 June 2022	100	23,100	475	1,455	(3,943)	**21,187**
Loss and total comprehensive loss for the period	—	—	—	—	(3,079)	**(3,079)**
Share based payments	—	—	215	—	—	**215**
Balance at 31 December 2022	100	23,100	690	1,455	(7,022)	**18,323**
Loss and total comprehensive loss for the period	—	—	—	—	(1,811)	**(1,811)**
Share based payments	—	—	47	—	—	**47**
Balance at 30 June 2023	100	23,100	737	1,455	(8,833)	**16,559**

Consolidated Statement of Cash Flows
For the six months to 30 June 2023

	Note	**Unaudited Six months to 30 June 2023 £'000**	Unaudited Six months to 30 June 2022 £'000	Audited Year ended 31 December 2022 £'000
Cash flows from operating activities				
Loss on ordinary activities before taxation		**(1,811)**	(1,707)	(4,777)
Adjustments for:				
Finance income		**(272)**	(45)	(209)
Amortisation	4	**13**	13	26
Share based payment expense		**47**	214	429
SME R&D tax credit	2	**—**	—	91
Movements in working capital and other adjustments:				
Change in trade and other receivables	5	**195**	(579)	(456)
Change in trade and other payables	6	**(455)**	389	528
Net cash flow used in operating activities		**(2,283)**	(1,715)	(4,368)
Cash flow from investing activities				
Payments for intangible assets	4	**(62)**	(385)	(597)
Interest received from bank		**272**	45	209
Net cash flow generated/(used) in investing activities		**210**	(340)	(388)
Net cash flow from financing activities		**—**	—	—
Net change in cash and cash equivalents		**(2,073)**	(2,055)	(4,756)
Cash and cash equivalents at beginning of period		**16,193**	20,949	20,949
Cash and cash equivalents at end of period		**14,120**	18,894	16,193

Notes to the Interim Results

1. General information

Poolbeg Pharma plc ("Poolbeg" or the "Company") is a public limited company incorporated in England and Wales with company number 13279507. The Company is quoted on the AIM market of the London Stock Exchange (ticker: POLB.L, ISIN: GB00BKPG7Z60) and traded 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

The Interim Results of the Company for the six months to 30 June 2023 comprise those of the Company and its subsidiaries (together the "Group"). The Interim Results have been prepared on the going concern basis under the historical cost convention in accordance with the recognition and measurement requirements of United Kingdom adopted International Financial Reporting Standards ("IFRS") and their interpretations issued by the International Accounting Standards Board ("IASB"), and in accordance with those parts of the Companies Act 2006 applicable to companies reporting under IFRS. As is permitted by the AIM rules, the Directors have not adopted the requirements of IAS 34 "Interim Financial Reporting" in preparing the financial statements. Accordingly, the financial statements are not in full compliance with IFRS and have neither been audited nor reviewed pursuant to guidance issued by the Auditing Practices Board.

The financial information for the six months to 30 June 2023 and 30 June 2022 is unaudited. The information for the year ended 31 December 2022 has been extracted from the Company's audited accounts on which the auditors issued an unqualified audit opinion. The information presented for that period does not constitute full accounts for that period. The 31 December 2022 audited accounts have been delivered to the Companies House.

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

The Interim Results were approved by the Board of Directors on 12 September 2023.

The accounting policies used in the preparation of the Interim Results are consistent with those used in the Company's audited financial statements for the year to 31 December 2022. The application of the accounting policies can involve significant estimation, uncertainty and critical judgement. The most significant judgement made in relation to the Interim Results is:

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 period and prior year has not been recognised in the Income Statement. R&D tax claims in relation to the 2022 tax year have been submitted by the Group and rebates in relation to that period are anticipated.

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.

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

	Unaudited Six months ended 30 June 2023	Unaudited Six months ended 30 June 2022	Audited Year ended 31 December 2022
Loss after tax attributable to equity holders of the Company (£'000)	**(1,811)**	(1,607)	(4,686)
Weighted average number of ordinary shares in issue	**500,000,000**	500,000,000	500,000,000
Fully diluted average number of ordinary shares in issue	**500,000,000**	500,000,000	500,000,000
Basic and diluted loss per share (pence)	**(0.36)**	(0.32)	(0.94)

Under IAS 33.43 "Earnings per Share", the calculation of loss per share does not assume conversion, exercise, or other issue of potential shares that would have an antidilutive effect on LPS. For the current and comparative periods, the effect of options would be to reduce the loss per share and as such the basic and diluted LPS are the same. There were 36,829,181 share options and warrants outstanding as at 30 June 2023 (30 June 2022 and 31 December 2022: 36,829,181) and these are potentially dilutive.

4. Intangible assets

	Acquired Licences & Data £'000	**Patents & Trademarks £'000**	**Total £'000**
Cost			
At 31 December 2021	1,500	81	**1,581**
Additions	435	162	**597**
At 31 December 2022	1,935	243	**2,178**
Additions	—	62	**62**
At 30 June 2023	**1,935**	**305**	**2,240**
Accumulated amortisation			
At 31 December 2021	18	—	**18**
Amortisation charge	25	1	**26**
At 31 December 2022	43	1	**44**
Amortisation charge	13	—	**13**
At 30 June 2023	**56**	**1**	**57**
Net book value			
Net book value at 30 June 2023	**1,879**	**304**	**2,183**
Net book value at 31 December 2022	1,892	242	2,134

Additions in the period relate to patent applications. Patents 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.

5 Trade and other receivables

	Unaudited 30 June 2023 £'000	Unaudited 30 June 2022 £'000	Audited 31 December 2022 £'000
Trade receivables	**6**	—	—
Prepayments and accrued income	**718**	990	878
VAT and corporation tax receivables	**43**	195	84
Trade and other receivables	**767**	1,185	962

6 Trade and other payables

	Unaudited 30 June 2023	Unaudited 30 June 2022	Audited 31 December 2022
	£'000	£'000	£'000
Trade payables	**124**	295	293
Accrued expenses	**321**	489	623
Other payables	**11**	9	4
Social security costs and other taxes	**55**	34	46
Trade and other payables	**511**	827	966

7. Events after the reporting period

None to report.

8. Copy of the interim results

A copy of the Company's Interim Results for the six months to 30 June 2023 is available on the Company's website, www.poolbegpharma.com/investors/documents/