Poolbeg Pharma plc - Interim results for the six months to 30 June 2024

Lead development candidate (POLB 001) on track with positive data demonstrating efficacy
Independent research endorses potential US$10bn market opportunity for POLB 001 in cancer immunotherapy-induced CRS
Patent portfolio significantly strengthened & expanded
Continued focus on high value programmes & partnerships to develop & commercialise assets
Strong Balance Sheet – cash balance of £10.1m
Experienced leadership team with track record of delivering significant value

18 September 2024– Poolbeg Pharma (AIM: POLB, 'Poolbeg' or the 'Company'), a clinical-stage biopharmaceutical company focussed on the development and commercialisation of innovative medicines targeting diseases with a high unmet medical need, announces its unaudited interim results for the six months to 30 June 2024 ("H1 24").

Highlights, Business Update & Outlook

- Cash balance of £10.1 million as at 30 June 2024, demonstrating continued prudent financial management
- Independent research has confirmed a potential market opportunity of c.US$10 billion for POLB 001 as an orally delivered preventative therapy for cancer immunotherapy-induced Cytokine Release Syndrome (CRS)[1]
- Robust data package in place for POLB 001 - efficacy demonstrated in reducing cancer immunotherapy-induced CRS in an *in vivo* animal model, strengthening and facilitating the expansion of patent applications
- US Patent Office granted the Company's Immunomodulator II patent application covering a class of drugs, including POLB 001, to treat or prevent hypercytokinemia (cytokine storm) induced in any disease indication
- Engagement continues with potential partners in relation to POLB 001
- Exclusive 12-month option agreement signed for tPTX, a novel, topical, muco-adherent treatment for oral ulcers in patients suffering from Behçet's Disease, with FDA Fast Track Designation, Orphan Drug Designation and potential 505(b)(2) approval pathway in the US
- Continued progress made in preparation for the upcoming orally-delivered, glucagon-like peptide 1 receptor agonist's (GLP-1R) clinical trial, expected to commence in late 2024
- Engaged with partners relating to drug targets and treatments identified in the Company's Artificial Intelligence (AI) led infectious-disease programmes
- Successful onboarding of a number of former Amryt Pharma senior executives. Amryt Pharma was a global, commercial-stage biopharmaceutical company dedicated to acquiring, developing and commercialising novel treatments for rare diseases. Previously listed on NASDAQ and AIM, it was acquired by Chiesi Farmaceutica for US$1.48 billion in 2023
- The strengthened Poolbeg team has a significant and successful track record of acquiring, integrating, partnering, developing and commercialising therapies for conditions with a high unmet medical need
- The Company strategy remains to partner in-house programmes to realise near-term value, while also targeting revenue generation and profitability from commercial-stage rare and orphan drugs

Jeremy Skillington, PhD, Chief Executive Officer of Poolbeg, commented: "*The value and attractiveness of POLB 001 to Pharma partners has been greatly enhanced following the independent confirmation of a potential market opportunity of c.US$10 billion as an oral preventative therapy for cancer immunotherapy-induced CRS. During the period, we also strengthened our patent and overall intellectual property portfolio with positive* in vivo *data. As Pharma companies seek to enhance the safety and market reach of their cancer immunotherapies, we believe that POLB 001 is well placed to generate value for shareholders while addressing a critical unmet medical need for patients.*

"Our increasing focus on rare and orphan diseases is exemplified by the exclusive option agreement we signed to acquire tPTX, which comes with robust clinical data, FDA Fast Track Designation, Orphan Drug Designation and the potential for a 505(b)(2) approval pathway in the US. tPTX has the potential to reach patients rapidly and offers a transformative solution for those suffering from Behçet's Disease.

"We continue to pursue our efforts to maximise the value of our development pipeline and are seeing significant interest from potential partners. Our experienced team, bolstered by the addition of a number of the former Amryt

leadership team, is well-positioned to execute on our strategy of acquiring, developing, partnering, and commercialising innovative medicines that will help improve the lives of patients with rare and orphan diseases, and where there is a high unmet medical need."

References

1. Independent research commissioned by Poolbeg

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About Poolbeg Pharma plc

Poolbeg Pharma plc is a clinical-stage biopharmaceutical company focussed on acquiring, developing and commercialising innovative medicines that will help improve the lives of patients with rare and orphan diseases and where there is a high unmet medical need. Poolbeg comprises a strong and growing portfolio of development assets. For more information, please go to www.poolbegpharma.com or follow us on Twitter and LinkedIn @PoolbegPharma.

Forward-Looking Statements

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

CEO Statement

I am delighted to present the unaudited Interim Financial Statements of Poolbeg Pharma plc for the six months to 30 June 2024.

A Growing Focus on Rare and Orphan Diseases

We are actively increasing our focus on rare and orphan diseases, leveraging both the expertise of the key former Amryt Pharma plc executives that joined Poolbeg in early 2024, and the potential of POLB 001 to address cancer immunotherapy-induced Cytokine Release Syndrome (CRS). We believe that there is potential for POLB 001 to be a rare and orphan therapy, as the patients receiving T cell engaging bispecific antibodies and CAR T-cell therapy are often suffering from rare or orphan blood cancers. Rare diseases affect a small percentage of the population, and due to the high unmet medical need, regulatory authorities offer significant incentives for developing orphan drugs. The orphan drug market is expected to grow to US$368 billion by 2030[2], with orphan drug sales due to account for 20% of global prescription drug sales by 2026[3]. With our Leadership Team's extensive expertise and proven track record in rare and orphan diseases, we believe Poolbeg is well-positioned to capitalise on these opportunities.

In April 2024, we signed an exclusive 12-month option agreement with Silk Road Therapeutics Inc. to acquire a novel, topical, muco-adherent formulation of Pentoxifylline (tPTX) for the treatment of oral ulcers in Behçet's Disease patients. This disease, which has no cure, causes severe inflammation leading to debilitating symptoms, the most common being painful oral ulcers which significantly impact essential functions like eating, drinking and speaking. tPTX has shown promising results in a Phase 2 trial, as presented at the American College of Rheumatology meeting in 2019, demonstrating faster healing and pain reduction compared to standard of care treatments. tPTX has secured FDA Fast Track and Orphan Drug Designation, providing seven years of market exclusivity upon marketing authorisation, and is potentially positioned for the expedited route to approval and commercialisation available via the 505(b)(2) pathway in the U.S.

Strong Progress Across our Pipeline of Assets

POLB 001 **–** A breakthrough preventative therapy for cancer immunotherapy-induced CRS, as well as a promising treatment for severe influenza. CRS affects over 70% of patients receiving T cell-engaging bispecific antibodies or CAR T-cell therapy.[4] With the cancer immunotherapy market expected to grow to US$120 billion by 2030[5, 6, 7], the need for effective CRS management is critical, as the condition currently leads to significant healthcare costs and restricts access to treatment at specialist cancer centres. Earlier this year, independent research commissioned by Poolbeg confirmed a market potential for POLB 001 of c.US$10 billion in Multiple Myeloma and Diffuse Large B-Cell Lymphoma alone due to the significant advances in bispecific antibody and CAR T-cell therapies for these indications.[8] Cancer immunotherapies are being widely developed across a broader range of haematological malignancies (including many rare or orphan cancers) and solid tumours, which we believe will expand the opportunity for POLB 001 far beyond the estimate of US$10 billion.

In January 2024, we announced positive *in vivo* results which demonstrated POLB 001's efficacy in reducing cancer immunotherapy-induced CRS symptoms in an animal model. The data strengthened and facilitated the expansion of patent applications for POLB 001 in cancer immunotherapy-induced CRS. We also convened an Independent Advisory Board with international Key Opinion Leaders, healthcare payers and clinical trial experts, which endorsed the attractiveness of POLB 001's Target Product Profile (TPP) and its potential as an oral therapy to address the significant unmet medical need of cancer immunotherapy-induced CRS.

In May 2024, we received the fully granted patent from the US Patent Office for our Immunomodulator II patent application, covering a class of drugs (including POLB 001) for treating hypercytokinemia (cytokine storm) and for preventing hypercytokinemia in a patient after an immune response has been triggered. This encompasses cytokine storm that is induced in any disease indication. Further patent applications have been filed and have complementary coverage as we continue to expand our existing patent portfolio covering POLB 001.

As an oral therapy to prevent or treat CRS, POLB 001 has the potential to enable broader use of cancer immunotherapies in an outpatient setting to make these life-saving therapeutics more accessible to patients. With robust data and intellectual property, and interest from scientific, clinical, and commercial partners to advance its development, we are excited by the potential of POLB 001 to have a meaningful impact on patients' lives while generating value for our shareholders.

Oral GLP-1R Agonist – With approximately 42% of the US population affected by obesity[9], the economic impact of the condition on US businesses and employees reached an estimated US$347.5 billion in 2023.[10] This has driven the growth of prescription weight loss drugs, particularly glucagon-like peptide 1 receptor agonists (GLP-1R), a market projected to reach US$150 billion by 2031.[11] Despite the demand, oral GLP-1R options are limited, with only one available drug offering just 1% bioavailability.[12] Our Oral GLP-1R agonist programme aims to address this unmet need using a delivery system that utilises Generally Regarded as Safe (GRAS) components to encapsulate API's (active pharmaceutical ingredients), such as GLP-1R agonist, for oral delivery to specific areas of the gut and into systemic circulation with the aim of enhancing bioavailability and improving convenience. We are progressing towards the initiation of a proof-of-technology clinical trial in late 2024 to demonstrate the successful delivery of an oral GLP-1R agonist in humans.

Artificial Intelligence – As part of our AI-led programmes, we have successfully identified valuable novel drug targets for influenza and new potential drug candidates for the treatment of Respiratory Syncytial Virus (RSV). Using our data-first approach, these novel targets are based on the host response to stop or slow disease progression. This strategy is less likely to be impacted by viral resistance versus traditional vaccines and antivirals, which target the virus itself. AI-led solutions typically enable faster target identification, at lower cost, reduced risk, and potentially increased likelihood of success. Having successfully prioritised candidates from both programmes late last year, and with continued global interest in AI-led drug discovery, we are continuing to actively discuss the exciting outputs from our AI-led drug discovery programmes with prospective partners.

Financial

Poolbeg had a cash balance of £10.1 million as at 30 June 2024. The loss for the period amounted to £2.3 million (H1 23: £1.8 million) comprised of R&D expenses of £0.7 million (H1 23: £0.9 million), administrative expenses £2.1 million (H1 23: £1.4 million), and tax rebates and other income & charges of £0.6 million (H1 23: £0.5 million).

Outlook

As we build on the momentum from H1 24, our focus remains on strategically partnering our in-house programmes to unlock near-term value, while also targeting future revenue generation and profitability from commercial-stage rare and orphan drugs. We are excited by the results of *in vivo* data demonstrating POLB 001's efficacy in reducing cancer immunotherapy-induced CRS and the potential for this market opportunity to generate value for shareholders while addressing a critical unmet medical need.

The option agreement signed with Silk Road Therapeutics underscores our commitment to strategic cash management by providing us the opportunity to evaluate the potential of the asset whilst preserving capital. This approach aligns with our disciplined financial strategy, ensuring that we continue to manage our resources effectively as we explore opportunities that could enhance our pipeline and deliver value to our shareholders. The addition of former Amryt Pharma team members, with proven experience in scaling a rare disease company and establishing commercial infrastructure in the US and globally, further strengthens our Leadership Team and our ability to execute on this growth strategy.

Jeremy Skillington, PhD
CEO
17 September 2024

References

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9. Stierman B, Afful J, Carroll MD, et al. National Health and Nutrition Examination Survey 2017–March 2020 prepandemic data files development of files and prevalence estimates for selected health outcomes. Natl Health Stat Report. 2021;158.
10. Global Data, Assessing the Economic Impact of Obesity and Overweight on Employers, Feb 2024
11. The Economist, March 2023
12. EMA Product information 2020

Consolidated Statement of Comprehensive Income

For the six months to 30 June 2024

	Note	**Unaudited Six months to 30 June 2024 £'000**	Unaudited Six months to 30 June 2023 £'000	Audited Year ended 31 December 2023 £'000
Revenue		**—**	—	—
Cost of sales		**—**	—	—
Gross profit		**—**	—	—
Administrative expenses		**(2,113)**	(1,395)	(3,376)
Other operating income		**285**	177	367
Research and development expenses		**(701)**	(865)	(1,677)
Impairment of intangible assets		**—**	—	(353)
Operating loss		**(2,529)**	(2,083)	(5,039)
Finance income		**246**	272	534
Loss before income tax		**(2,283)**	(1,811)	(4,505)
Taxation		**25**	—	574
Loss and total comprehensive loss for the period attributable to the equity holders of the Company		**(2,258)**	(1,811)	(3,931)
Loss per share:				
Loss per share – basic and diluted, attributable to ordinary equity holders of the parent	3	**(0.45)p**	(0.36)p	(0.79)p

Consolidated Statement of Financial Position

As at 30 June 2024

	Note	**Unaudited 30 June 2024 £'000**	Unaudited 30 June 2023 £'000	Audited 31 December 2023 £'000
Assets				
Non-current assets				
Intangible assets	5	**2,011**	2,183	1,930
Total non-current assets		**2,011**	2,183	1,930
Current assets				
Trade and other receivables	6	**938**	767	1,327
Cash and cash equivalents		**10,061**	14,120	12,171
Total current assets		**10,999**	14,887	13,498
Total assets		**13,010**	17,070	15,428
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		**2,460**	2,192	2,195
Accumulated deficit		**(13,211)**	(8,833)	(10,953)
Total equity		**12,449**	16,559	14,442
Current liabilities				
Trade and other payables		**561**	511	986
Total current liabilities		**561**	511	986
Total liabilities		**561**	511	986
Total equity and liabilities		**13,010**	17,070	15,428

Consolidated Statement of Changes in Equity

For the six months to 30 June 2024

	Share capital £'000	Share premium £'000	Share based payment reserve £'000	Merger reserve £'000	Accumulated deficit £'000	Total £'000
At 1 January 2023	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**
Loss and total comprehensive loss for the period	—	—	—	—	(2,120)	**(2,120)**
Share based payments	—	—	3	—	—	**3**
Balance at 31 December 2023	100	23,100	740	1,455	(10,953)	**14,442**
Loss and total comprehensive loss for the period	—	—	—	—	(2,258)	**(2,258)**
Share based payments	—	—	265	—	—	**265**
Balance at 30 June 2024	100	23,100	1,005	1,455	(13,211)	**12,449**

Consolidated Statement of Cash Flows

For the six months to 30 June 2024

	Note	**Unaudited Six months to 30 June 2024 £'000**	Unaudited Six months to 30 June 2023 £'000	Audited Year ended 31 December 2023 £'000
Cash flows from operating activities				
Loss on ordinary activities before taxation		**(2,283)**	(1,811)	(4,505)
Amortisation	5	**13**	13	26
Impairment of intangible assets		**—**	—	353
Share based payment expense	4	**265**	47	50
Finance income		**(246)**	(272)	(534)
R&D tax credits		**424**	—	—
Movements in working capital and other adjustments:				
Change in trade and other receivables	6	**(10)**	195	209
Change in trade and other payables		**(425)**	(455)	20
Net cash flow used in operating activities		**(2,262)**	(2,283)	(4,381)
Cash flow from investing activities				
Payments for intangible assets	5	**(94)**	(62)	(175)
Interest received from bank		**246**	272	534
Net cash flow generated in investing activities		**152**	210	359
Net cash flow from financing activities		**—**	—	—
Net change in cash and cash equivalents		**(2,110)**	(2,073)	(4,022)
Cash and cash equivalents at beginning of period		**12,171**	16,193	16,193
Cash and cash equivalents at end of period		**10,061**	14,120	12,171

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 listed on the AIM market of the London Stock Exchange (ticker: POLB.L, ISIN: GB00BKPG7Z60).

Poolbeg is a clinical-stage biopharmaceutical company focussed on acquiring, developing and commercialising innovative medicines that will help improve the lives of patients with rare and orphan diseases and where there is a high unmet medical need.

2. Basis of preparation

The Interim Results of the Company for the six months to 30 June 2024 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 2024 and 30 June 2023 is unaudited. The information for the year ended 31 December 2023 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 2023 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 17 September 2024.

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 2023. 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:

Share based payments: in the current period, the Company 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 a suitable valuation model as a proxy. Estimating fair value requires determination of the most appropriate valuation model, which depends on the terms and conditions of the grant. For the measurement of the fair value of share options issued under the Employee Performance Incentive Plan ("EIP") a Monte-Carlo simulation model was used.

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 2024	Unaudited Six months ended 30 June 2023	Audited Year ended 31 December 2023
Loss after tax attributable to equity holders of the Company (£'000)	**(2,258)**	(1,811)	(3,931)
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	**(0.45)p**	(0.36)p	(0.79)p

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 65,076,600 share options and warrants outstanding as at 30 June 2024 (30 June 2023 and 31 December 2023: 36,829,181) and these are potentially dilutive.

4. Share-based payments

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

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 Units	**Warrants Units**
Balance at 31 December 2022, 30 June 2023 & 31 December 2023	36,000,000	829,181
Granted during the period to 30 June 2024	28,247,419	—
Balance at 30 June 2024	**64,247,419**	**829,181**

The fair value of the share options granted during the period, was estimated at the date of grant using a Monte-Carlo simulation model, taking into account the terms and conditions attached to the grant.

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

	Unaudited Six months to 30 June 2024 £'000	Unaudited Six months to 30 June 2023 £'000	Audited Year ended 31 December 2023 £'000
Share options	**265**	47	50
Total	**265**	47	50

5. Intangible assets

	Acquired Licences & Data £'000	Patents & Trademarks £'000	Total £'000
Cost			
At 31 December 2022	1,935	243	**2,178**
Additions	29	146	**175**
At 31 December 2023	**1,964**	**389**	**2,353**
Additions	—	94	**94**
At 30 June 2024	**1,964**	**483**	**2,447**
Amortisation and impairment			
At 31 December 2022	43	1	**44**
Amortisation charge	25	1	**26**
Impairment	250	103	**353**
At 31 December 2023	**318**	**105**	**423**
Amortisation charge	12	1	**13**
At 30 June 2024	**330**	**106**	**436**
Net book value			
Net book value at 30 June 2024	**1,634**	**377**	**2,011**
Net book value at 31 December 2023	1,646	284	1,930

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.

6 Trade and other receivables

	Unaudited 30 June 2024 £'000	Unaudited 30 June 2023 £'000	Audited 31 December 2023 £'000
Trade receivables	**11**	6	—
Prepayments and accrued income	**627**	718	669
Grant receivable	**75**	—	31
VAT recoverable	**50**	43	53
R&D tax credit	**175**	—	574
Trade and other receivables	**938**	767	1,327

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 2024 is available on the Company's website, www.poolbegpharma.com/investors/documents/