

Poolbeg Pharma plc

Interim results for the six months to 30 June 2022

Significant strategic and operational progress

6 September 2022 – Poolbeg Pharma (AIM: POLB, OTCQB: POLBF, 'Poolbeg' or the 'Company'), a clinical stage infectious disease pharmaceutical company with a unique capital light clinical model, announces its unaudited interim results for the six months to 30 June 2022.

Financial & Operational Highlights

- Well capitalised with a strong cash balance of £18.9m as at 30 June 2022
- Significant progress made on developing POLB 001, a treatment for severe influenza
 - LPS human challenge trial commenced in July 2022 with initial results expected by year end 2022
 - Supply Agreement signed and GMP manufacturing completed
 - Key US patent granted in May 2022
 - Continuing to explore further disease indications beyond severe influenza
- Two AI programmes commenced to analyse Poolbeg's unique human challenge trial data
 - Agreement signed with OneThree Biotech Inc. in February 2022 to identify new drug targets and treatments for Respiratory Syncytial Virus (RSV). The programme is progressing well with the model build and optimisation completed in June 2022, with results expected by the end of 2022
 - In March 2022 an agreement was signed with CytoReason Ltd. to identify novel drug targets for influenza. Data analysis is ongoing, and results are expected in Q2 2023
- Licensed first-in-class broad spectrum RNA-based immunotherapy (POLB 002) for respiratory virus infections from the University of Warwick in January 2022
 - Key European and US patents granted in April and May 2022 respectively
- Diligence completed on POLB 003, an intramuscular vaccine candidate to prevent Melioidosis from University College Dublin. Definitive license agreement being finalised following exclusive option agreement (signed in December 2021)
- Licensed AnaBio Technologies' micro- and nanoencapsulation technology to develop oral vaccines in January 2022

Investor presentation

Jeremy Skillington, PhD, Chief Executive Officer, will provide a live presentation via the Investor Meet Company platform on **6 September 2022 at 6:00pm**.

The presentation is open to all existing and potential shareholders. Investors can sign up to Investor Meet Company for free and add to meet **Poolbeg Pharma plc** [here](#). The presentation and recording will be available on the Company's website after the event [here](#).

Jeremy Skillington, PhD, CEO of Poolbeg Pharma said: *"I am pleased with the progress that the team has made to advance and expand our portfolio of products and platforms, and we intend to build on and accelerate this rate of progress in the remainder of 2022 and beyond.*

Poolbeg is entering a very exciting phase in its development with a number of near-term value inflection points expected before year end. This includes the initial results from our LPS human challenge trial for our severe influenza treatment, POLB 001, after which we will seek to out-licence to pharma and biotech companies, generating revenues from upfront payment and downstream milestones and royalties. In addition, the outputs from our RSV and influenza Artificial Intelligence Programmes are expected by the end of 2022 and in Q2 2023 respectively.

We have strong financial resources available to progress our products and platforms and also to capitalise on new opportunities as we identify them which, in addition to our upcoming value inflection points, gives me confidence that we can generate strong returns for shareholders."

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About Poolbeg Pharma

Poolbeg Pharma is a clinical stage infectious disease pharmaceutical company, with a unique capital light clinical model which aims to develop multiple products faster and more cost effectively than the conventional biotech model. The Company, headquartered in London, is led by a team with a track record of creation and delivery of shareholder value and aspires to become a “one-stop shop” for pharma and biotech seeking mid-stage products to license or acquire.

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.

With its initial assets from [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 (POLB 001) which has commenced its LPS human challenge trial with initial results expected by year end 2022; 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 an oral vaccine delivery platform and is progressing two artificial intelligence (AI) programmes to accelerate the power of its human challenge model data and biobank, with results from the first programme expected by year end 2022.

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

CEO's 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 2022. Poolbeg has made significant strides in our first 12 months since IPO on 19 July 2021.

Strong progress across the pipeline

- **POLB 001** – a p38 MAP Kinase inhibitor for the treatment of severe Influenza, remains on track for initial results by the end of 2022 following the commencement of the bacterial lipopolysaccharide (LPS) human challenge trial. In July 2022, Poolbeg received ethics and competent authority approval to commence the trial following completion of the various preparatory steps including executing a Clinical Trial Agreement, a GMP Supply Agreement and the subsequent completion of GMP manufacturing whilst also achieving a key US patent grant in May 2022.

The trial will provide key human data on the efficacy of POLB 001 in treating patients with severe influenza, using LPS as a surrogate. The trial will efficiently, and cost effectively collect both local and systemic efficacy data creating a comprehensive data package which will be attractive to potential partners. Poolbeg then intends to partner or out-license POLB 001 and initial interactions with potential partners is progressing positively. The Company continues to explore potential new disease indications for POLB 001 beyond severe influenza, which could greatly increase the value of the asset.

- **POLB 002** – a first-in-class, intranasally administered, RNA-based immunotherapy for respiratory virus infections in-licensed in January 2022. As a nasally administered and rapidly effective prophylactic antiviral candidate, it could potentially provide an effective solution for protecting at risk patient populations. Key US and European patents were granted in H1 2022 to support the development of POLB 002.
- **POLB 003** – having completed due diligence, the Company is now converting the exclusive option agreement (signed in December 2021) to a definitive agreement with University College Dublin to licence this intramuscular vaccine candidate to prevent Melioidosis, a disease predominately found in tropical and sub-tropical regions. As part of the ongoing relationship with UCD, Poolbeg retains an exclusive option agreement and continues to evaluate five additional bacterial vaccine candidates.
- **Oral Vaccine Delivery Platform** – in January 2022 Poolbeg licensed AnaBio Technologies' micro- and nanoencapsulation technology to develop oral vaccines. This oral vaccine platform delivers immune stimulating antigens to specific areas of the gut with the objective of activating protective 'mucosal immunity' to prevent pathogens from infecting the body. Oral vaccines can significantly reduce distribution and administration challenges thereby enhancing vaccine uptake making it a very attractive platform for partnering.
- **RSV Artificial Intelligence Programme** – signed an agreement with [OneThree Biotech Inc.](#) in February 2022 to identify new drug targets and treatments for Respiratory Syncytial Virus ('RSV') through analysis of Poolbeg's unique human challenge trial data and publicly available datasets by OneThree's clinically validated artificial intelligence technology. The programme is progressing well with the model build and optimisation completed in June 2022, with results expected by the end of 2022.
- **Influenza Artificial Intelligence Programme** – signed an agreement with [CytoReason Ltd](#), a leading AI company, in March 2022 to utilise Poolbeg's unique repository of clinical samples and associated data from influenza human challenge trials along with CytoReason's existing clinical data to help identify novel drug targets for influenza. Results are expected in Q2 2023 and Poolbeg looks forward to updating the market as to the progress of this programme.
- **Business Development** – Poolbeg continues to identify and conduct diligence on a range of other opportunities, while the management team looks to expand the existing products and platforms to new areas and evaluate other applications for its unique databank.

Corporate & Financial

Poolbeg remains well capitalised with a strong cash balance of £18.9m as at 30 June 2022. Loss for the period amounted to £1.6m; comprising R&D expenses of £0.7m, administrative expenses of £1.2m and other income & tax rebates of £0.3m.

Poolbeg successfully commenced trading on the OTCQB Venture Market in the United States in March 2022. The OTC Market allows the Company access to one of the world's largest investment markets and fits with our long-term strategy and ambitions to be dual listed on a national securities exchange in the US, such as Nasdaq, subject to meeting their listing requirements.

Outlook

During the period, the Company has made significant strides in growing and progressing the pipeline of products and platforms and intends to build on and accelerate this progress for the remainder of 2022 and beyond.

Poolbeg is entering a very exciting phase of its development with a number of near-term value inflection points, including the initial results from our first clinical study for POLB 001, expected by the end of the year. In addition, the outputs from our RSV and influenza Artificial Intelligence Programmes are expected by year end 2022 and in Q2 2023 respectively.

The Company has strong financial resources available to progress the existing pipeline and to explore and develop new opportunities to address the growing need for new infectious disease vaccines and treatments. As such, this gives me great confidence that Poolbeg can generate strong returns for shareholders over the coming years.

Jeremy Skillington, PhD

Chief Executive Officer

6 September 2022

Consolidated Statement of Comprehensive Income

For the six months to 30 June 2022

	Note	Unaudited Six months to 30 June 2022 £'000	Audited Period ended 31 December 2021 £'000
Revenue		—	—
Cost of sales		—	—
Gross profit		—	—
Administrative expenses		(1,228)	(2,031)
Other operating income		133	109
Research and development expenses		(657)	(414)
Operating loss		(1,752)	(2,336)
Finance income		45	—
Loss on ordinary activities before taxation		(1,707)	(2,336)
Tax credit on loss on ordinary activities	4	100	—
Loss and total comprehensive loss for the period attributable to the equity holders of the Company		(1,607)	(2,336)
Loss per share:			
Loss per share – basic and diluted, attributable to ordinary equity holders of the parent (pence)	3	(0.32)	(0.74)

Consolidated Statement of Financial Position

As at 30 June 2022

	Note	Unaudited 30 June 2022 £'000	Audited 31 December 2021 £'000
Assets			
Non-current assets			
Intangible assets	5	1,935	1,563
Total non-current assets		1,935	1,563
Current assets			
Trade and other receivables	6	1,185	506
Cash and cash equivalents		18,894	20,949
Total current assets		20,079	21,455
Total assets		22,014	23,018
Equity and liabilities			
Equity attributable to owners of the parent			
Share capital		100	100
Share premium		23,100	23,100
Other reserves		1,930	1,716
Accumulated deficit		(3,943)	(2,336)
Total equity		21,187	22,580
Current liabilities			
Trade and other payables		827	438
Total current liabilities		827	438
Total liabilities		827	438
Total equity and liabilities		22,014	23,018

Consolidated Statement of Changes in Equity

For the six months to 30 June 2022

	Share capital £'000	Share premium £'000	Share based payment reserve £'000	Merger reserve £'000	Accumulated deficit £'000	Total £'000
Loss and total comprehensive loss for the period	—	—	—	—	(2,336)	(2,336)
Issue of shares as part of demerger	45	—	—	1,455	—	1,500
Issue of shares for cash	55	24,950	—	—	—	25,005
Costs charged against share premium	—	(1,829)	—	—	—	(1,829)
Share based payments	—	(21)	261	—	—	240
Balance at 31 December 2021	100	23,100	261	1,455	(2,336)	22,580
Loss and total comprehensive loss for the 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

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

Consolidated Statement of Cash Flows

For the six months to 30 June 2022

	Note	Unaudited Six months to 30 June 2022 £'000	Audited Period ended 31 December 2021 £'000
Cash flows from operating activities			
Loss on ordinary activities before taxation		(1,707)	(2,336)
<i>Adjustments for:</i>			
Finance income		(45)	—
Amortisation	5	13	18
Share based payment expense		214	240
<i>Movements in working capital and other adjustments:</i>			
Change in trade and other receivables		(579)	(506)
Change in trade and other payables		389	438
Net cash flow used in operating activities		(1,715)	(2,146)
Cash flow from investing activities			
Payments for intangible assets	5	(385)	(81)
Interest received		45	—
Net cash flow used in investing activities		(340)	(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		(2,055)	20,949
Cash and cash equivalents at beginning of period		20,949	—
Cash and cash equivalents at end of period		18,894	20,949

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).

Poolbeg is a clinical stage infectious diseases pharmaceutical company, with a capital light model which aims to develop multiple products faster and more cost effectively than the conventional biotech model.

2. Basis of preparation

The Interim Results of the Company for the six months to 30 June 2022 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 accounting policies used in the preparation of the Interim Results are consistent with those used in the Company’s audited financial statements for the period to 31 December 2021.

The financial information for the six months to 30 June 2022 is unaudited. The comparative financial information is for the period from incorporation on 19 March 2021 to 31 December 2021 and 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 2021 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 Financial Statements were approved by the Board of Directors on 5 September 2022.

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
19 March 2021 - Issue of shares on incorporation	5,000 ^A	
20 May 2021 - Issue of shares – share placing	24,992,500	
18 June 2021 - Issue of shares on acquisition of ORPH Pharma IP Company Limited	225,002,500	
16 July 2021 - Issue of shares – EIS/VCT	23,010,000	
19 July 2021 - Issue of shares – share placing on IPO	226,990,000	
31 December 2021	500,000,000	317,227,413
30 June 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:

	Unaudited Six months ended 30 June 2022	Audited Period ended 31 December 2021
Loss after tax attributable to equity holders of the Company (£'000)	(1,607)	(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)	(0.32)	(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 and prior period, 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 2022 (31 December 2021: 36,829,181) and these are potentially dilutive.

4. Tax on ordinary activities

Poolbeg, through its subsidiary ORPH Pharma IP Company Limited, is entitled to claim tax credits in the United Kingdom under the small and medium enterprises (SME) research and development (R&D) tax relief scheme. This scheme provides additional taxation relief for qualifying expenditure on R&D activities and includes an option to surrender a portion of tax losses arising from qualifying activities in return for a cash payment.

The income statement for the six months to 30 June 2022 reflects the £90,000 R&D tax credit for the period to 31 December 2021 which was received in August 2022. In addition, an accrual of £10,000 has been included in respect of the six months to 30 June 2022, no claim has yet been made in relation to 2022 and the company continues to review changes to the SME R&D tax relief scheme which includes a measure to, if certain exemptions are not met, cap SME claims to £20,000 plus 300% of total Pay as you Earn (PAYE) and National Insurance Contributions (NIC) liability for the relevant period covered by the claim. The changes to the scheme effect Poolbeg with effect from the accounting period commencing on 1 January 2022.

No corporation tax charge arises in the six months to 30 June 2022. A split of the current tax credit appears below:

	Unaudited Six months to 30 June 2022 £'000	Audited Period ended 31 December 2021 £'000
Current tax		
UK corporation tax on losses for the period	—	—
UK SME R&D tax credit receivable in relation to the prior period	90	—
UK SME R&D tax credit receivable for current period	10	—
Total tax credit on loss on ordinary activities	100	—

5. Intangible assets

	Acquired Licences & Data £'000	Patents & Trademarks £'000	Total £'000
Cost			
Acquired from hVIVO Services Limited	1,500	—	1,500
Other additions	—	81	81
At 31 December 2021	1,500	81	1,581
Additions	291	94	385
At 30 June 2022	1,791	175	1,966
Accumulated amortisation			
Amortisation charge	18	—	18
At 31 December 2021	18	—	18
Amortisation charge	13	—	13
At 30 June 2022	31	—	31
Net book value			
Net book value at 30 June 2022	1,760	175	1,935
Net book value at 31 December 2021	1,482	81	1,563

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 has been charged to administrative expenses in the Statement of Comprehensive Income.

The prior period acquired licences & data additions, £1,500,000, relates to the value of intangible assets acquired from hVIVO Services Limited by ORPH Pharma IP Company Limited as part of the demerger process from Open Orphan plc. £1,250,000 of these assets are currently not being amortised as it is the Company's policy not to amortise assets in development that are not ready for use. The remaining £250,000 of assets acquired which relates to licences for certain data and samples are being amortised over a 10 year period from the date of acquisition. The acquired licences & data in the current period, £291,000, relates to upfront and other fees paid as part of licensing agreements entered. These licensed assets are not currently ready for use and are not being amortised.

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

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

6. Trade and other receivables

	Unaudited 30 June 2022 £'000	Audited 31 December 2021 £'000
Trade receivables	—	8
Prepayments and accrued income	259	449
VAT and corporation tax receivables	195	49
Clinical trial and collaboration agreement prepayments	731	—
Total trade and other receivables	1,185	506

Clinical trial and collaboration agreement prepayments relate to upfront payments made for research activity to external partners and will be expensed in the income statement over the period of the research activity.

7. Events after the reporting period

On 22 July 2022 clinical trial activities commenced in relation to the POLB 001 LPS human challenge trial. Initial results are expected by year end 2022.

8. Copy of the interim results

A copy of the Company's Interim Results for the six months to 30 June 2022 is available on the Company's website, www.poolbegpharma.com/investors/documents/