

Company Registration Number: 13279216

ORPH Pharma IP Company Limited

**Reports & Financial Statements
for the year ended
31 December 2022**

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ORPH Pharma IP Company Limited

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ORPH Pharma IP Company Limited

Directors' Report

For the year ended 31 December 2022

The directors of ORPH Pharma IP Company Limited (the "Company" or "ORPH IP") presents his report and the Financial Statements of the Company for the year ended 31 December 2022. The Company is registered in England and Wales, having been incorporated as a private company limited by shares with registered number 13279216.

Principal Activity, Review of Business and Future Developments

The principal activity of the Company is the research and development of vaccines and treatments for infectious and other prevalent diseases. The Company has a unique capital light model which aims to develop multiple products faster and more cost effectively than the conventional biotech model with plans to rapidly monetise its products to pharmaceutical and biotechnology companies.

The Company has made substantial progress since its incorporation in March 2021. In the current year, this included securing an exclusive licence for POLB 002 (an RNA-based immunotherapy for respiratory virus infections) and commencing exciting collaborations with two leading biotech biology driven Artificial Intelligence ("AI") specialists.

During 2022, operational highlights include the completion of our bacterial lipopolysaccharide "LPS" human challenge trial for POLB 001 which demonstrated that POLB 001 was shown to be 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 ORPH IP as it demonstrated POLB 001's expected utility in severe influenza and supports continued development in other acute inflammatory conditions.

ORPH IP, 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.

Research and Development

Currently 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 £2,066,000 (2021: £388,000) expensed in the current year.

ORPH IP files patents in key global territories to protect its early-stage product pipeline and continually reviews opportunities for IP expansion in relation to its products. ORPH IP continuously assesses its patent portfolio and maintains an active vigilance program to identify instances where a third party may be infringing on its intellectual property.

Results and Dividends

The loss for the year, after taxation amounted to £2,325,000 (2021: £585,000). The director does not recommended the payment of a dividend.

Directors

The directors who served during the year and to the date of this report are as follows:

Director	Capacity	
Cathal Friel	Chairman	
Jeremy Skillington	Chief Executive Officer	Appointed 9 May 2023
Ian O'Connell	Chief Financial Officer	Appointed 9 May 2023

Directors' Report*For the year ended December 2022***Directors and their Interests**

At year end, the Directors of the Company, did not hold any interest in ORPH IP. The Directors held the following interest in Poolbeg Pharma plc ("Poolbeg", together with its subsidiary companies "Poolbeg Group"), the ultimate parent company of the Company:

Director	%	Date of this report Number	31 December 2022 Number	31 December 2021 Number
Cathal Friel	7.28	36,389,757	36,389,757	36,389,757
Jeremy Skillington	0.14	718,733	N/A	N/A
Ian O'Connell	1.67	8,326,839	N/A	N/A

Share options and warrants

The Directors of the Company held the following share option and warrants of Poolbeg Pharma plc:

Director	Type	At 31 December 2021 & 2022 Number	Exercise price	Grant Date	Expiry Date
Cathal Friel	Warrants	240,681	£0.10	13/07/2021	18/07/2026
Cathal Friel ^A	Share Options	3,500,000	£0.10	13/07/2021	12/07/2031
Cathal Friel ^B	Share Options	3,500,000	£0.15	13/07/2021	12/07/2031
Cathal Friel ^C	Share Options	3,500,000	£0.15	13/07/2021	12/07/2031
Jeremy Skillington ^A	Share Options	5,000,000	£0.10	13/07/2021	12/07/2031
Jeremy Skillington ^B	Share Options	5,000,000	£0.15	13/07/2021	12/07/2031
Jeremy Skillington ^C	Share Options	5,000,000	£0.15	13/07/2021	12/07/2031
Ian O'Connell ^A	Share Options	3,500,000	£0.10	13/07/2021	12/07/2031
Ian O'Connell ^B	Share Options	3,500,000	£0.15	13/07/2021	12/07/2031
Ian O'Connell ^C	Share Options	3,500,000	£0.15	13/07/2021	12/07/2031
		36,240,681			

^A The closing share price must be at least £0.10 for five consecutive business days when exercised. The option holder must be employed by the Group on the 12 month anniversary of AIM admission and cannot have given or received notice of termination of employment on or before such date

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

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

Qualifying Indemnity Provision

Poolbeg Group has in place insurance protection, including a Directors and Officers liability policy, to cover the risk of loss when management deems it appropriate and cost effective; however, in some cases risks cannot be effectively covered by insurance and the cover in place may not be sufficient to cover the extent of potential liabilities.

Going Concern

Whilst COVID-19, and the associated uncertainties are now receding, the conflict in eastern Europe, accompanied by rising inflation, interest rates and a broad degree of macro-economic and political disruption continue to create challenges for the global economy. The Group itself is well capitalised and debt-free, meaning it is able to benefit from rising interest rates on its cash reserves without any exposure to increased costs of debt. Suppliers and key stakeholders have all made adjustments to

Directors' Report

For the year ended December 2022

minimise disruptions and to facilitate the continued efficient running of their businesses and the Company does not foresee any significant problems in relation to its operations in the coming year.

The Company's forecasts and projections reflect the plans for the coming year and include spend in relation to progressing POLB 001 along the clinical pathway for severe influenza and as a CAR T cell companion therapy, ongoing research spend in relation to POLB 002 in order to move it towards the clinic and additional spend on the asset pipeline including advancing the Company's AI data powered drug programmes following receipt of programme outputs in 2023. The Company performs sensitivity analysis on its projected cashflows and when performing these sensitivities it takes into account reasonable changes in market conditions.

After making appropriate enquires, the directors consider that the Company has adequate resources to continue in business for the foreseeable future. Accordingly, they continue to adopt the going concern basis in preparing the Financial Statements.

Principal Risks and Uncertainties

The Company is subject to a range of risk factors relating to the business and its operations in the biotechnology/pharmaceutical industry. ORPH IP's success is rooted in its ability to identify and de-risk products in the infectious disease space and to develop these products to the point of out-licensing.

Organisational Risk

ORPH IP's future success is dependent on the experience and skills of the management team to successfully execute its strategy. The loss of key contributors would present a risk to the business. Finding and hiring any additional personnel and replacements could be a costly and time consuming process, particularly in the biotechnology/pharmaceutical industry.

Competition Risk

The biotechnology and pharmaceutical industries are very competitive. ORPH IP's competitors include major multinational pharmaceutical companies, biotechnology companies and research institutions. Many of its competitors have substantially greater financial, technical and other resources, such as larger research and development staff. ORPH IP's competitors may succeed in developing, acquiring or licensing drug product candidates that are earlier to market, more effective or less costly than any product candidate which ORPH IP is currently developing or which it may develop and this may have a material adverse impact on the ORPH IP.

Development Risk

ORPH IP has a number of drug candidates in various stages of clinical and pre-clinical development. Our management team understand that a high incidence of delay or failure to produce valuable scientific results will not support ORPH IP's strategy.

Clinical trials can be expensive, time consuming and difficult to design and implement and involve uncertain outcomes. Furthermore, results of earlier pre-clinical studies and clinical trials may not be predictive of results of future pre-clinical studies or clinical trials.

Regulatory Risk

The regulatory approval processes of the EMA, FDA, MHRA and other comparable regulatory agencies may be lengthy, time-consuming and the outcome is unpredictable. ORPH IP's future success is dependent upon its ability to rapidly develop and out-license its product candidates.

Directors' Report

For the year ended December 2022

In addition, positive human efficacy data does not guarantee that a product will be out-licensed by ORPH IP.

Intellectual Property Risk

If the Company is unable to obtain, maintain, defend or enforce the intellectual property rights covering its products, third parties may be able to make, dispose (or offer to dispose) of, use, import or keep products that would otherwise infringe the Company's patents and which would materially adversely affect the Company's ability to compete in the market.

Patent protection is important for ORPH IP's competitive position in its planned product lines and a failure to obtain or retain adequate protection could have a material adverse effect on the Company's business, prospects, financial condition and/or results of operations.

Funding Risk

Developing pharmaceutical products requires significant funding to bring the product to the point of monetisation. ORPH IP may need to raise additional funding to undertake development work and bring our products to the point of monetisation.

There is also no certainty that it will be possible to raise any additional funds at all or on acceptable terms. Debt financing, may place restrictions on the financial operating activities of the Company and if ORPH IP is unable to obtain additional financing, it may be required to reduce the scope of its operation

Pandemic, macro-economic and geopolitical Risk

There is an ongoing risk to Poolbeg due to unexpected global events that may negatively impact its ability to operate.

This includes the outbreak of future strains of SARS-CoV-2 or escalation of geopolitical events in Europe. Such events have led to high rates of inflation, exchange rate volatility, higher cybersecurity risk and supply chain disruptions and could adversely impact Poolbeg's business, including executing of our preclinical studies and clinical trials.

Financial Risk

The financial risk management objectives and policies of the Company are detailed in note 13 of the Notes to the Financial Statements.

Political Donations

The Company made no political donations during the year.

Events after the Reporting Period

Events after the reporting period are set out in note 16 to the Financial Statements. Likely future developments in the business are discussed in the Directors' Report.

Auditors

Gravita Audit Limited (formerly Jeffreys Henry Audit Ltd) have expressed their willingness to continue in office as auditor, and a resolution to reappoint Gravita Audit Limited, will be proposed at the forthcoming Annual General Meeting.

Directors' Report

For the year ended December 2022

Small Companies Exemption

This report has been prepared in accordance with the provisions applicable to companies entitled to the Small Companies Exemption.

Disclosure of Information to the Auditors

The Directors confirms that: (a) he has taken all the steps that he ought to have taken to make himself aware of any information needed by the Company's auditors for the purposes of their audit and to establish that the auditors are aware of that information and (b) so far as he is aware there is no relevant audit information of which the auditors are unaware.

Directors' Responsibilities

The directors are responsible for preparing the Directors' Report and the Financial Statements in accordance with applicable law and regulations.

Company law requires the directors to prepare Financial Statements for each financial year. Under that law the directors have elected to prepare the Company Financial Statements in accordance with FRS 101 Reduced Disclosure Framework ('FRS 101') as adopted by the United Kingdom in conformity with the requirements of the Companies Act 2006. Under company law the directors must not approve the Financial Statements unless they are satisfied that they give a true and fair view of the state of affairs of the Company and of the profit or loss of the Company for that period.

In preparing these Financial Statements, the directors are required to:

- select suitable accounting policies and then apply them consistently;
- make judgements and accounting estimates that are reasonable and prudent;
- state whether they have been prepared in accordance with applicable IFRSs, subject to any material departures disclosed and explained in the Financial Statements;
- prepare the Financial Statements on the going concern basis unless it is inappropriate to presume that the company will continue in business.

The directors are responsible for keeping adequate accounting records that are sufficient to show and explain the Company's transactions and disclose with reasonable accuracy at any time the financial position of the Company and enable them to ensure that the Financial Statements comply with the requirements of the Companies Act 2006. The directors are also responsible for safeguarding the assets of the Company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

This report was approved by the Board on 16 May 2023 and signed on its behalf by:



Ian O'Connell
Director

Independent auditor's Report to the Members of ORPH Pharma IP Company Limited

Opinion

We have audited the financial statements of ORPH Pharma IP Company Limited for the year ended 31 December 2022 which comprise the statement of comprehensive income, the statement of financial position, the statement of changes in equity and notes to the financial statements, including a summary of significant accounting policies.

The financial reporting framework that has been applied in the preparation of the financial statements is applicable law and United Kingdom Accounting Standards, including FRS101 The Financial Reporting Standard applicable in the UK and Republic of Ireland (United Kingdom Generally Accepted Accounting Practice).

In our opinion:

- the financial statements give a true and fair view of the state of the Company's affairs as at 31 December 2022 and of the Company's loss for the period then ended;
- the financial statements have been properly prepared in accordance with United Kingdom Generally Accepted Accounting Practice; and
- the financial statements have been prepared in accordance with the requirements of the Companies Act 2006.

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (UK) (ISAs (UK)) and applicable law. Our responsibilities under those standards are further described in the Auditor's responsibilities for the audit of the financial statements section of our report. We are independent of the Company in accordance with the ethical requirements that are relevant to our audit of the financial statements in the UK, including the FRC's Ethical Standard, and we have fulfilled our other ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Conclusions relating to going concern

In auditing the financial statements, we have concluded that the directors' use of the going concern basis of accounting in the preparation of the financial statements is appropriate. Our evaluation of the directors' assessment of the entity's ability to continue to adopt the going concern basis of accounting included reviews of expected cash flows for a period of 12 months, to determine expected cash outflow, which was compared to the liquid assets held in the entity.

Based on the work we have performed, we have not identified any material uncertainties relating to events or conditions that, individually or collectively, may cast significant doubt on the company's ability to continue as a going concern for a period of at least twelve months from when the financial statements are authorised for issue.

Our responsibilities and the responsibilities of the directors with respect to going concern are described in the relevant sections of this report.

Other information

The directors are responsible for the other information. The other information comprises the information included in the annual report, other than the financial statements and our auditor's report thereon. Our opinion on the financial statements does not cover the other information and, except to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon.

Independent Auditor's Report

For the year ended 31 December 2022

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated. If we identify such material inconsistencies or apparent material misstatements, we are required to determine whether there is a material misstatement in the financial statements or a material misstatement of the other information. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Opinions on other matters prescribed by the Companies Act 2006

In our opinion, based on the work undertaken in the course of the audit:

- the information given in the Directors' report for the financial year for which the financial statements are prepared is consistent with the financial statements; and
- the Directors' report has been prepared in accordance with applicable legal requirements.

Matters on which we are required to report by exception

In the light of the knowledge and understanding of the Company and its environment obtained in the course of the audit, we have not identified material misstatements in the Directors' report.

We have nothing to report in respect of the following matters in relation to which the Companies Act 2006 requires us to report to you if, in our opinion:

- adequate accounting records have not been kept by the Company, or returns adequate for our audit have not been received from branches not visited by us; or
- the financial statements are not in agreement with the accounting records and returns; or
- certain disclosures of the Directors' remuneration specified by law are not made; or
- we have not received all the information and explanations we require for our audit.
- the directors were not entitled to prepare the financial statements in accordance with the small companies' regime, and take advantage of the small companies' exemption in preparing the Directors' Report and take advantage of the small companies' exemption from the requirement to prepare a Strategic Report

Responsibilities of Directors

As explained more fully in the Directors' responsibilities statement set out on page 5, the Directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view, and for such internal control as the Directors determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the Directors are responsible for assessing the Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the Directors either intends to liquidate the Company or to cease operations, or have no realistic alternative but to do so.

Auditor's responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance about whether the financial statements, as a whole, are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (UK) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

Independent Auditor's Report

For the year ended 31 December 2022

Irregularities, including fraud, are instances of non-compliance with laws and regulations. We design procedures in line with our responsibilities, outlined above, to detect material misstatements in respect of irregularities, including fraud. The extent to which our procedures are capable of detecting irregularities, including fraud, is detailed below.

Explanation as to what extent the audit was considered capable of detecting irregularities, including fraud

The objectives of our audit, in respect to fraud are; to identify and assess the risks of material misstatement of the financial statements due to fraud; to obtain sufficient appropriate audit evidence regarding the assessed risks of material misstatements due to fraud, through designing and implementing appropriate responses; and to respond appropriately to fraud or suspected fraud identified during the audit. However, the primary responsibility for the prevention and detection of fraud rests with both those charged with governance of the entity and management.

Our approach to identifying and assessing the risks of material misstatement in respect of irregularities, including fraud and non-compliance with laws and regulations, was as follows:

- the senior statutory auditor ensured the engagement team collectively had the appropriate competence, capabilities and skills to identify or recognise non-compliance with applicable laws and regulations;
- we identified the laws and regulations applicable to the company through discussions with directors and other management, and from our knowledge and experience of the entity's activities.
- we focused on specific laws and regulations which we considered may have a direct material effect on the financial statements or the operations of the company, including Companies Act 2006, taxation legislation, data protection, employment and health and safety legislation.
- we assessed the extent of compliance with the laws and regulations identified above through making enquiries of management and reviewing legal expenditure; and
- identified laws and regulations were communicated within the audit team regularly and the team remained alert to instances of non-compliance throughout the audit.

We assessed the susceptibility of the company's financial statements to material misstatement, including obtaining an understanding of how fraud might occur, by:

- making enquiries of management as to where they considered there was susceptibility to fraud, their knowledge of actual, suspected and alleged fraud; and
- considering the internal controls in place to mitigate risks of fraud and non-compliance with laws and regulations.

To address the risk of fraud through management bias and override of controls, we:

- performed analytical procedures to identify any unusual or unexpected relationships;
- tested journal entries to identify unusual transactions;
- assessed whether judgements and assumptions made in determining the accounting estimates were indicative of potential bias; and
- investigated the rationale behind significant or unusual transactions.

In response to the risk of irregularities and non-compliance with laws and regulations, we designed procedures which included, but were not limited to:

- agreeing financial statement disclosures to underlying supporting documentation;
- reading the minutes of meetings of those charged with governance; and
- enquiring of management as to actual and potential litigation and claims

There are inherent limitations in our audit procedures described above. The more removed that laws and regulations are from financial transactions, the less likely it is that we would become aware of non-compliance. Auditing standards also limit the audit procedures required to identify non-compliance with laws and regulations to enquiry of the directors and other management and the inspection of regulatory and legal correspondence, if any.

Material misstatements that arise due to fraud can be harder to detect than those that arise from error as they may involve deliberate concealment or collusion.

ORPH Pharma IP Company Limited

Independent Auditor's Report


For the year ended 31 December 2022

A further description of our responsibilities for the audit of the financial statements is located on the Financial Reporting Council's website at: www.frc.org.uk/auditorsresponsibilities.

This description forms part of our auditor's report.

Use of this report

This report is made solely to the Company's members, as a body, in accordance with Chapter 3 of Part 16 of the Companies Act 2006. Our audit work has been undertaken so that we might state to the Company's members those matters we are required to state to them in an auditor's report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the Company and the Company's members as a body, for our audit work, for this report, or for the opinions we have formed.



Sachin Ramaiya (Senior Statutory Auditor)

For and on behalf of

Gravita Audit Ltd, Statutory Auditor

Finsgate

5-7 Cranwood Street

London EC1V 9EE

16 May 2023

ORPH Pharma IP Company Limited

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		227	189
Research and development expenses	2	2,066	388
Operating loss		2,293	577
Finance expense	3	123	8
Loss on ordinary activities before taxation	3	2,416	585
Taxation	5	(91)	—
Loss and total comprehensive loss for the period attributable to the equity holders of the Company		2,325	585

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.

ORPH Pharma IP Company Limited


Statement of Financial Position

As at 31 December 2022

	Note	31 December 2022 £'000	31 December 2021 £'000
Assets			
Non-current assets			
Intangible assets	6	1,862	1,563
Total non-current assets		1,862	1,563
Current assets			
Trade and other receivables	7	478	62
Amounts owed by group undertakings	8	—	10
Cash and cash equivalents	9	254	98
Total current assets		732	170
Total assets		2,594	1,733
Equity and liabilities			
Equity attributable to owners of the parent			
Share capital	10	1,500	1,500
Accumulated deficit		(2,910)	(585)
Total equity		(1,410)	915
Non-current liabilities			
Amounts owed to group undertakings	12	3,493	649
Total current liabilities		3,493	649
Current liabilities			
Trade and other payables	11	511	169
Total current liabilities		511	169
Total liabilities		4,004	818
Total equity and liabilities		2,594	1,733

The Financial Statements set out on pages 11 to 23 were approved and authorised for issue on 16 May 2023.

They are signed on the Board's behalf by:



Ian O'Connell
Director

Company Number
13279216

ORPH Pharma IP Company Limited

Statement of Changes in Equity

For the year ended 31 December 2022

	Note	Share capital £'000	Accumulated deficit £'000	Total £'000
Loss and total comprehensive loss for the period		—	(585)	(585)
Issue of shares on acquisition of intangible assets from hVIVO Services Ltd	10	1,500	—	1,500
Balance at 31 December 2021		1,500	(585)	915
Loss and total comprehensive loss for the year		—	(2,325)	(2,325)
Balance at 31 December 2022		1,500	(2,910)	(1,410)

Notes to the Financial Statements

1 General information

ORPH Pharma IP Company Limited ("ORPH IP" or the "Company") is a private limited company incorporated in England and Wales with company number 13279216. 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.

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

2 Accounting policies

Basis of preparation

The financial statements are prepared in accordance with FRS 101 Reduced Disclosure Framework ('FRS 101'). In these financial statements, the Company has applied the exemptions available under FRS 101 in respect of the following disclosures:

- A cash flow statement and related notes;
- Disclosures in respect of transactions with group companies;
- Disclosures in respect of the compensation of Key Management Personnel;
- Disclosure in respect of capital management; and
- The effects of new but not yet effective IFRSs.

The Company's ultimate beneficial owner is Poolbeg Pharma plc ('Poolbeg'). Copies of Poolbeg's consolidated financial statements are filed with the Companies House in the UK.

Going concern

Management believe that it is appropriate to prepare these consolidated financial statements on the going concern basis. In making that assessment, management are required to consider whether the Company can continue in operational existence for the foreseeable future, being a period of not less than twelve months from the date of the approval of the financial statements. In reaching the going concern conclusion, the Company considered the support provided by its parent company and its parents' cash and cash equivalents of £16.1m as at 31 December 2022 and the Company's forecasts and projections over the 24 months from period end, along with sensitivity analysis performed on the projected cashflows taking into account reasonable changes in market conditions. Management also considered, Poolbeg Group's ability to successfully operate during the COVID-19 pandemic as demonstrated by it completing an IPO and raising £25m before costs. This provides the Company with access to funding to ensure that its commitments are met as they fall due. Accordingly, the Directors continue to adopt the going concern basis in preparing the Financial Statements.

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.

The following table discloses the major exchange rates of those currencies utilised by the Company:

Foreign currency units to 1 £	€	US\$
Average year to 31 December 2022	1.1702	1.2101
At 31 December 2022	1.1284	1.2329

(US\$ = US Dollars; € = Euro)

Notes to the Financial Statements

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

(US\$ = US Dollars; € = Euro)

Comparative period

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

Accounting policies and disclosures

The accounting policies adopted are consistent throughout the financial period. Standards and amendments to IFRS effective as of 1 January 2022 have been applied by the Company unless they have been exempted under FRS 101.

Critical accounting judgements and key sources of estimation uncertainty

The preparation of Financial Statements in conformity with IFRS requires management to make estimates and judgements that affect the reported amounts of assets and liabilities as well as the disclosure of contingent assets and liabilities at the period end and the reported amounts of revenues and expenses during the reporting period. Estimates and judgements are continually evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances.

The Company's accounting policy descriptions set out the areas that involve significant estimation, uncertainty and critical judgement. The most significant of which are:

(a) Impairment of Intangible Assets

The Company tests annually whether intangibles have suffered any impairment, in accordance with the accounting policy stated in note 2. The valuation uses an income approach, discounted cash flows, for valuing the carrying value of intangible assets based on assumptions within the forecast based on market inputs. Sensitivities have been applied regarding likelihood of the drug reaching the next development milestone. These calculations require the use of estimates as set out in note 6. The Company tests annually whether there is any indication that Intangible Assets have been impaired.

(b) Research and development ("R&D") tax credits:

R&D tax claims can be complex and require management to make significant assumptions in building the methodology for the claim, interpreting research and development tax legislation to the Company's specific circumstances, and agreeing the basis of the tax computations with HM Revenue & Customs. As the Company has not yet built up a track record of R&D tax credit receipts, an estimation of the potential R&D tax credit receivable for the current year has not been recognised in the Income Statement.

Principal accounting policies

The principal accounting policies are summarised below. They have been consistently applied throughout the period covered by the Financial Statements.

Research and development expenses

The costs relating to the development of products are accounted for in accordance with IAS 38 "Intangible Assets", where they meet the criteria for capitalisation.

Development costs are capitalised as an intangible asset if all of the following criteria are met:

1. The technical feasibility of completing the asset so that it will be available for use or sale;
2. The intention to complete the asset and use or sell it;

Notes to the Financial Statements

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 £2,066,000 (2021: £388,000) 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.

Financial instruments

Financial instruments are classified on initial recognition as financial assets, financial liabilities or equity instruments in accordance with the substance of the contractual arrangement. Financial instruments are initially recognised when the Company becomes party to the contractual provisions of the instrument. Financial assets are de-recognised when the contractual rights to the cash flows from the financial asset expire or when the contractual rights to those assets are transferred. Financial liabilities are de-recognised when the obligation specified in the contract is discharged, cancelled or expired.

Financial assets

Cash and cash equivalents

Cash comprises bank balances, all of which are available without notice.

Trade and other receivables

Trade and other receivables have fixed or determinable payments that are not quoted in an active market, are measured at initial recognition at fair value, and are subsequently measured at amortised costs using the effective interest method less impairment. Trade and other receivables are reduced by appropriate allowances for estimated irrecoverable amounts. Interest income is recognised by applying the effective interest rate, except for short-term receivables when the recognition of interest would be immaterial.

Impairment of financial assets

At each statement of financial position date, financial assets are assessed for indicators of impairment. Financial assets are impaired if indications exist that events have occurred after the initial recognition of the financial asset that estimated future cash flows have been impacted. If any such indication exists, the recoverable amount of the asset is estimated in order to determine the extent of the impairment loss. Where the asset does not generate cash flows that are independent from other assets, the Company estimates the recoverable amount of the cash-generating unit to which the asset belongs. Any impairment loss arising from the review is charged to the statement of comprehensive

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income whenever the carrying amount of the asset exceeds its recoverable amount.

Financial liabilities

Trade and other payables

Trade and other payables are initially measured at their fair value and are subsequently measured at their amortised cost using the effective interest rate method except for short-term payables when the recognition of interest would be immaterial.

Foreign currency translation

The Company translates foreign currency transactions into its functional currency, £, at the rate of exchange prevailing at the transaction date. Monetary assets and liabilities denominated in foreign currencies are translated into the functional currency at the rate of exchange prevailing at the Statement of Financial Position date. Exchange differences arising are taken to the Statement of Comprehensive Income. Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates at the dates of the initial transactions.

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 Company expects to derive economic benefit. Certain licences for data and samples are being amortised over a 10 year period from the date of acquisition.

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.

Impairment

At each Statement of Financial Position date, the Company reviews the carrying amounts of its acquired intangible assets to determine whether there is any indication that those assets have suffered an impairment loss. If any such indication exists, the recoverable amount of the asset is estimated in order to determine the extent of the impairment loss. Any impairment loss arising from the review is charged to the Statement of Comprehensive Income whenever the carrying amount of the asset exceeds its recoverable amount.

The Company assesses each asset or cash-generating unit annually to determine whether any indication of impairment exists. Where an indicator of impairment exists, a formal estimate of the recoverable amount is made, which is considered to be the higher of the fair value less costs to sell and value in use. These assessments require the use of estimates and assumptions such as discount rates, future capital requirements, general risks affecting the pharmaceutical industry and other risks specific to the individual asset. Fair value is determined as the amount that would be obtained from the sale of the asset in an arm's length transaction between knowledgeable and willing parties. Fair value is generally determined as the present value of estimated future cash flows arising from the continued use of the asset, using assumptions that an independent market participant may take into account. Cash flows are discounted to their present value using a pre-tax discount rate that reflects

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current market assessments of the time value of money and the risks specific to the asset. Assets are grouped into the smallest group that generate cash inflows are independent of other assets.

Taxes

Tax comprises current and deferred tax. Current tax is the expected tax payable on the taxable income for the period, using tax rates enacted or substantially enacted at the reporting date. Deferred tax assets or liabilities are recognised where the carrying value of an asset or liability in the Statement of Financial Position differs to its tax base, and is accounted for using the statement of financial position liability method. Recognition of deferred tax assets is restricted to those instances where it is probable that taxable profit will be available against which the difference can be utilised.

Where eligible the Company applies for R&D tax credits. As the Company 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 Operating loss

	Year to 31 December 2022 £'000	Period to 31 December 2021 £'000
Operating loss for the period is stated after charging:		
Fees payable to the Company's auditor for audit of the Company's annual accounts	5	4
Fees payable to the Company's auditor for other services:		
Tax compliance services	—	1
Amortisation of intangible assets	18	18
Loan interest charged by parent company	123	8
Foreign exchange losses	17	1

4 Employees

The Company's average number of employees, including the directors, during the period was 1 (2021: 1). No remuneration was received by the directors from the Company. All directors' fees are paid at the Poolbeg Group level.

5 Taxation

The current year tax credit is made up as follows:

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

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A reconciliation of the expected tax benefit computed by applying the tax rate applicable in the United Kingdom, to the loss before tax to the actual tax credit is as follows:

	Year to 31 December 2022 £'000	Period to 31 December 2021 £'000
Loss before tax	(2,416)	(585)
Tax credit at normal rate of UK corporation tax of 19%	(459)	(111)
Effect of:		
Losses unutilised	459	111
Prior period adjustments	(91)	—
Current tax credit for the period	91	—

The Company has tax losses of up to £1,299,015 (2021: £585,000) to carry forward against future profits. The deferred tax asset on tax losses at 25% of £325,000 (2021: £111,000 at 19%) has not been recognised due to the uncertainty of the recovery.

The Company qualifies for HMRC's SME R&D tax relief scheme which allows it to deduct an extra 130% of its qualifying costs against its tax position. As the Company is loss making it elects to claim receivable tax credits under the scheme, which are calculated as 14.5% of the surrenderable loss, instead of carrying forward the enhanced R&D relief as additional tax losses.

6 Intangible Assets

	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	163	162	325
At 31 December 2022	1,663	243	1,906
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	1,620	242	1,862
Net book value at 31 December 2021	1,482	81	1,563

The Company 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

Notes to the Financial Statements

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

7 Trade and other receivables

	31 December 2022 £'000	31 December 2021 £'000
Prepayments	457	36
VAT recoverable	21	26
Trade and other receivables	478	62

8 Amounts owed by group undertakings

	31 December 2022 £'000	31 December 2021 £'000
Total amounts owed by group undertakings	—	10

9 Cash and cash equivalents

	31 December 2022 £'000	31 December 2021 £'000
Total Cash and cash equivalents	254	98

10 Issued share capital and other reserves

Details of ordinary shares of £1 each issued are in the table below:

	Number of ordinary shares	Share Capital £'000
Issued during 2021	1,500,001	1,500
At 31 December 2021	1,500,001	1,500
At 31 December 2022	1,500,001	1,500

No shares were issued during the year. As is permitted under the Companies Act 2006, the Company does not have authorised share capital.

Other reserves

Share capital represents the cumulative par value arising upon issue of ordinary shares of £1 each.

Accumulated deficit represents losses accumulated in the current year and prior periods.

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11 Trade and other payables

	31 December 2022 £'000	31 December 2021 £'000
Trade payables	252	68
Accrued expenses	157	19
Other payables	1	—
Social security costs and other taxes	6	—
Amounts due to parent company	25	25
Amounts due to group company	70	57
Trade and other payables	511	169

The purchases from related parties were undertaken on normal commercial terms in the ordinary course of the company's business. Outstanding balances at the year-end are unsecured, interest free and settlement occurs in cash.

12 Amounts owed to group undertakings

	31 December 2022 £'000	31 December 2021 £'000
Total amounts owed to group undertakings	3,493	649

Amounts owed to group undertakings pertains to amounts obtained by the Company from its parent company to sustain the Company's working capital requirements. The amounts due are subject to interest.

13 Financial risk management

The Company is exposed to risks that arise as a result of its use of financial instruments. Details of the financial instruments generated during the Company's activities are below:

Categories of Company financial instruments

	31 December 2022 £'000	31 December 2021 £'000
Financial assets (all at amortised cost):		
Cash and cash equivalents	254	98
Total financial assets	254	98
Financial liabilities (all at amortised cost):		
Trade payables and accrued expenses	505	169
Total financial liabilities	505	169
Net	(251)	(71)

The directors consider that the carrying values of all financial assets and liabilities shown above to be the fair value of the Company's assets and liabilities.

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Policies and Objectives

The Company's operations expose it to some financial risks arising from its use of financial instruments, the most significant ones being liquidity, market risk and credit risk. The directors are responsible for the Company's risk management policies and whilst retaining responsibility for them has delegated the authority for designing and operating processes that ensure the effective implementation of the objectives and policies to the Company's finance function. The main policies for managing these risks are as follows:

Liquidity risk

The Company is not subject to any externally imposed capital requirement, accordingly the Company's objectives when managing capital are to safeguard the ability to continue as a going concern in order to provide returns for shareholders and benefits to other stakeholders and to maintain an optimal capital structure to reduce the cost of capital. Working capital forecasts are prepared to ensure the Company has sufficient funds to complete contracted work commitments.

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

	Less than 1 month £'000	Between 1 and 3 months £'000	Between 3 and 6 months £'000	Total £'000
31 December 2022				
Current liabilities	388	109	14	511

	Less than 1 month £'000	Between 1 and 3 months £'000	Between 3 and 6 months £'000	Total £'000
31 December 2021				
Current liabilities	77	87	5	169

Market risk

Market risk arises from the use of interest bearing financial instruments and represents the risk that future cash flows of a financial instrument will fluctuate as a result of changes in interest rates. It is the Company's policy to ensure that significant contracts are entered into in its functional currency whenever possible and to maintain the majority of cash balances in the functional currency of the Company. The Company considers this policy minimises any unnecessary foreign exchange exposure.

During the period, the Company did not earn interest on its financial assets. The effect of a 1% change in interest rates obtainable during the period on cash balances would be to increase or decrease the Company loss before tax by £1,000.

In addition to cash balances maintained in £, the Company had balances in € at period-end. A theoretical 10% adverse movement in the period end £:€ exchange rate would lead to an increase in the Company loss before tax by £15,000 with a corresponding reduction in the Company loss before tax with a 10% favourable movement.

Credit risk

Credit risk is the risk that the counterparty will default on its contractual obligations resulting in financial loss. Credit risk arises from cash and cash equivalents and from exposure via deposits with the Company's bankers. For cash and cash equivalents, the Company only uses recognised banks with high credit ratings.

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14 Capital commitments and contingencies

The Company has no material capital commitments at the year end.

As part of its regular business the Company 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.

15 Immediate parent and ultimate holding company

The company's immediate parent and ultimate holding company is Poolbeg Pharma plc, a company registered in England and Wales. Poolbeg Pharma plc's registered office is Queen Mary BioEnterprises Innovation Centre, 42 New Road, London E1 2AX United Kingdom. Copies of Poolbeg Pharma plc's Annual Report are available to download from its website at www.poolbegpharma.com.

16 Events after the reporting period

ORPH IP'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, ORPH IP 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, ORPH IP 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, ORPH IP 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, ORPH IP 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.

17 Related party transactions

The Company has taken advantage of the exemptions laid out in Financial Reporting Standard 101 that allow it not to disclose transactions with entities that are part of the group on the grounds that consolidated financial statements of the group are publicly available.

ORPH Pharma IP Company Limited

Company Information

Registered Office

Queen Mary BioEnterprises Innovation Centre
42 New Road
London E1 2AX
United Kingdom

Company Number

13279216

Directors

Cathal Friel
Jeremy Skillington
Ian O'Connell

Company Secretary

Ross Crockett

Company Website

www.poolbegpharma.com

Solicitors

DAC Beachcroft
The Wallbrook Building
25 Wallbrook
London, EC4N 8AF
United Kingdom

Auditors

Gravita Audit Limited
Finsgate
5-7 Cranwood Street
London, EC1V 9EE
United Kingdom