RNS Number: 7366A Polarean Imaging PLC 26 May 2023



## Polarean Imaging Plc

("Polarean" or the "Company")

#### Final results for the year ended 31 December 2022

Notice of Annual General Meeting

Polarean Imaging plc (AIM: POLX), the medical imaging company announces its audited final results for the year ended 31 December 2022

In addition, Polarean confirms that the Annual Report and Accounts for the year ended 31 December 2022, the Notice of the Annual General Meeting ("AGM") and a Form of Proxy are now available on the Company's website <a href="http://www.polareanir.com/content/investors/annual-reports.asp">http://www.polareanir.com/content/investors/annual-reports.asp</a>) and will be posted to shareholders shortly.

The AGM will be held at 2500 Meridian Parkway, Suite 175, Durham, NC 27713, USA at 2 p.m. BST / 9 a.m. EST on 28 June 2023.

#### Highlights

- United States Food and Drug Administration ("FDA") approval received for the Company's drug device combination product, XENOVIEW (xenon Xe 129 hyperpolarised), a hyperpolarised contrast agent indicated for use with magnetic resonance imaging ("MRI") for evaluation of lung ventilation in adults and pediatric patients aged 12 years and older
- Simultaneously with the approval of the XENOVIEW NDA, two 510(k) devices were cleared by the FDAKENOVIEW VDP is image processing software that analyses a pulmonary hyperpolarised 129-Xe MR image and a proton chest MR image to provide visualisation and evaluation of lung ventilation and the Polarean XENOVIEW 3.0T Chest Coil
- Research system placements at McMaster University in Ontario, Canadaand Cincinnati Children's Hospital Medical Center ("CCHMC")
- Appointment of Frank Schulkes, Dan Brague and Marcella Ruddy, MD to the Board as independent Non-Executive Directors
- Appointment of Ken West as Non-Executive Chairman, following the retirement of Jonathan Allis
- $\hbox{-} \quad \hbox{Research collaboration with Oxford University Hospitals NHS Trust for long-COVID}\\$
- Net cash of US\$16.4 million as of 31 December 2022

## Post-period end

- First order for a XENOVIEW gas blend cylinder for the production of XENOVIEW received from CCHMC, representing key milestone and execution of commercial plan
- First clinical scan utilising XENOVIEW technology in the United States conducted at CCHMC, marking key milestone for imaging of lung ventilation
- Selected as one of the featured companies as a poster presenter at the American Thoracic Society's ("ATS") 2023 Respiratory Innovation Summit

Richard Hullihen, CEO of Polarean, said: "We ended the year with a tremendous positive in receiving our FDA approval for XENOVIEW. This was a long road culminating with the decision we were looking for, and an extraordinary amount of work went into this process from the entire team. We have now begun to roll out XENOVIEW for clinical use and expect to see further hospitals adopt doing clinical XENOVIEW scans in the coming months. We alsocontinue to explore potential future applications for our technology and remain positive for the year ahead. Separately, we have been shortlisted for Breakthrough of the Year and Best Technology at the 2023 European Mediscience Awards, which celebrates private and listed healthcare, biotech and life sciences companies; we are delighted by this validation of our technology and our achievement in securing FDA approval, and are excited to see the outcome.

"On behalf of the Board and the whole Polarean team, I would like to extend my thanks to our shareholders for all their support and we look forward to further updating the market in due course."

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) 596/2014.

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Polarean Imaging plc

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#### About Polarean (www.polarean.com)

The Company and its wholly owned subsidiary, Polarean, Inc. (together the "Group") are revenue-generating, medical imaging technology companies operating in the high-resolution medical imaging space. Polarean aspires to revolutionise pulmonary medicine by bringing the power and safety of MRI to the respiratory healthcare community in need of new solutions to evaluate lung ventilation, diagnose disease, characterise disease progression, and monitor response to treatment. By researching, developing, and commercialising novel imaging solutions with a non-invasive and radiation-free functional imaging platform. Polarean's vision is to help address the global unmet medical needs of more than 500 million patients worldwide suffering with chronic respiratory disease. Polarean is a leader in the field of hyperpolarisation science and has successfully developed the first and only hyperpolarised MRI contrast agent to be approved in the United States. On Dec. 23, 2022, the FDA granted approval for Polarean's first drug device combination product, XENOVIEWM (Xenon Xe<sup>129</sup> hyperpolarised). Xe<sup>129</sup> MRI is also currently being studied for visualisation and quantification of gas exchange regionally in the smallest airways of the lungs, across the alveolar tissue membrane, and into the pulmonary bloodstream for future clinical indications.

#### **XENOVIEW IMPORTANT SAFETY INFORMATION**

#### **Warnings and Precautions**

Risk of Decreased Image Quality from Supplemental Oxygen: Supplemental oxygen administered simultaneously with XENOVIEW<sup>TM</sup> inhalation can cause degradation of image quality. For patients on supplemental oxygen, withhold oxygen inhalation for two breaths prior to XENOVIEW<sup>TM</sup> inhalation, and resume oxygen inhalation immediately following the imaging breath hold.

Risk of Transient Hypoxia: Inhalation of an anoxic gas such as XENOVIEW<sup>TM</sup> may cause transient hypoxemia in susceptible patients. Monitor all patients for oxygen desaturation and symptoms of hypoxemia and treat as clinically indicated.

#### **Adverse Reactions**

Adverse Reactions in Adult Patients: The adverse reactions (> one patient) in efficacy trials were oropharyngeal pain, headache, and dizziness. Adverse Reactions in Pediatric and Adolescent Patients: In published literature in pediatric patients aged 6 to 18, transient adverse reactions were reported: blood oxygen desaturation, heart rate elevation, numbness, tingling, dizziness, and euphoria. In at least one published study of pediatric patients aged 6 to 18 years, transient decrease in SpO2% and transient increase in heart rate was reported following hyperpolarized xenon Xe 129 administration. XENOVIEW<sup>TM</sup> is not approved for use in pediatric patients less than 12 years of age.

Please see full prescribing information at www.xenoview.net

## Chairman's Statement

I am pleased to be able to write this letter with the very important milestone of United States Food & Drug Administration ("FDA") approval of the Company's drug device combination product, XENOVIEW, having been accomplished. The broad label of "evaluation of lung ventilation in adults and pediatric patients aged 12 years and older" allows the company to execute its commercial strategy of selling its polarizer and approved gas for clinical scans of patients suffering from a number of lung diseases where the accurate measurement of lung ventilation provides the physician with actionable diagnostic information. In addition, researchers using Polarean's technology continue to conduct clinical research that supports the broad future potential applications of our technology in areas of gas exchange and cardiopulmonary diagnostics. We are excited to bring Polarean's technology to clinical medicine, with the potential to be an important part of pulmonary and cardiopulmonary diagnostics, monitoring of severity of disease and patient response to treatments.

During 2022, we strengthened our Board with the addition of three independent Non-Executive Board members who bring extensive industry and medical experience to the Board to assist the company's successful transition into the commercialization stage. Frank Schulkes brings substantial financing experience in the medical imaging industry and Dan Brague brings experience successfully commercializing diagnostic imaging products. In addition, Dr. Marcella Ruddy brings important pulmonary medical expertise, both in clinical practice and in pharmaceutical development. With these additions to our Board, we believe that we have a world-class Board that can lead the company to successful commercialization of Xenoview.

Having achieved FDA approval, our efforts are now focused on gaining commercial traction and engaging with potential corporate partners to further accelerate our commercial success. Once we have achieved some of these near-term milestones, we will explore the options for additional financing to more aggressively pursue the development of the next indications and advance the continued development of our polarizer system and software. The Company is exploring a broad range of options for future financing, including equity raises and corporate partnering.

On behalf of the Board, I want to thank our employees, stakeholders and shareholders and assure them that we are committed to making Xenoview a commercial and financial success.

# Kenneth West

Non-Executive Chairman 25 May 2023

#### Chief Executive Officer's Statement

#### 2022 - Year of Obtaining FDA Approval

We spent much of 2022 working on obtaining FDA approval of our New Drug Application ("NDA") for XENOVIEW and were please received our approval on 23 December 2022. After receiving a Complete Response Letter ("CRL") from the FDA in October 2021, we spend the subsequent six months addressing the issues raised in the CRL. On 30 March 2022, the Company refiled the NDA with the FDA. The resubmission addressed the items identified in the CRL. On 22 September the Company announced that the FDA had requested additional information related to the cGMP (Current Good Manufacturing Practice) pre-approval inspection at the partner's production facility. The Company and its partner addressed the FDA's request and the Company received FDA approval on 23 December 2022. We were very pleased to receive the broad label of evaluation of lung function in adults and pediatric patients twelve and older. In addition, the FDA indicated that they would allow us to submit a non-clinical plan to obtain approval in pediatric patients six and older. The FDA has granted New Chemical Entity ("NCE") designation for Xenoview. NCE designation provides the important first mover protection envisioned under the Hatch Waxman legislation.

#### Commercialization

With FDA approval, the Company is focused on successful commercialization of XENOVIEW for the evaluation of lung function. The Company has an enthusiastic base of US institutions who have been using our technology for research purposes for years. We are leveraging this knowledge and enthusiasm by converting its US research sites to FDA approved configuration and clinical use, which will allow these sites to purchase Xenoview and perform clinical scans. In parallel, we are pursuing various reimbursement codes that could enable the hospitals to be reimbursed for Xenoview, the polarization process, the MRI procedure and the analysis of the pulmonary function imaging. If obtained, we believe that this reimbursement would enable a very compelling return on investment for hospitals to purchase our polarizer systems. We are aggressively pursuing our early commercialization targets of the sale of 15 to 20 polariser systems and 75 to 100 cylinders of Xenoview by the end of 2024.

We are focusing initially on addressing the high end of the US academic and teaching hospital market segment, which comprises approximately the top 1000 institutions nationally having coincident multiple Centres of Excellence in Pulmonary Medicine and Radiology. We believe our strategy of selling the capital equipment and the Xenoview drug on a per cylinder basis could provide a capital equipment and recurring drug sales model that supports rapidly growing revenue.

#### Financials

Sales for 2022 were below our original expectations, as we did not receive FDA approval in October 2022 as anticipated in the plan. We adjusted our spending plans commensurate with the delayed approval, which allowed us to finish 2022 with a higher than anticipated cash balance of US\$16.4 million. We continued to sell our polariser systems into the research market and completed two installations during 2022. The current cash balance is expected to fund the company into late Q2-2024.

## **Corporate Partnering**

We continue to believe that corporate partnering could be an important part of the Company's business plan. We see the opportunity to help the pharmaceutical industry reduce by significant amounts the size, time required to conduct and costs of their pulmonary drug clinical trials by providing quantitative, reproducible image-based data. We also see the opportunity to partner with MRI manufacturers to open up the MRI applications space to include pulmonary diagnostics, driving the demand for more MRI systems. In addition, we will explore the opportunity to partner with pulmonary disease organizations and foundations to incorporate the use of Xenoview in the diagnosis and treatment of disease.

## **Future Indications**

Researchers are currently conducting clinical trials and pharmaceutical company sponsored investigations in multiple areas of pulmonary disease using our technology. These studies are highlighting the exciting opportunities in the areas of long COVID and cardiopulmonary vascular disease. We believe that these areas could greatly expand the total addressable markets and use of the Company's technology in the future.

## 2023 and Beyond

As discussed above, we are focused on achieving early commercial traction with our broad lung function evaluation label granted by the FDA in late 2022. In parallel, we are exploring a variety of partnering opportunities. Once we have achieved some of these near-term milestones, we will explore the appropriate timing and structure to finance the continued commercial efforts, clinical trials to seek approval for the high-value gas exchange and pulmonary vascular disease indications and continue to improve our polariser system and imaging software.

This important milestone of FDA approval would not have been possible without the dedicated team of employees, consultants and advisers working to bring our much needed technology to clinicians, their patients and the institutions enabling their care. I thank everyone for their hard work in accomplishing this significant achievement.

## Richard Hullihen

Chief Executive Officer 25 May 2023

#### **Strategic Report**

#### 1. Introduction

The Group comprises medical drug-device combination companies operating in the high-resolution medical imaging market. The Group develops equipment that enables existing MRI systems to achieve an improved level of pulmonary functional imaging and specialises in the use of polarised xenon gas (129Xe) as an imaging agent to visualise ventilation (the ability of air to reach the alveoli) and gas exchange (the ability of oxygen to diffuse through the alveolar membrane into the pulmonary vasculature) regionally down to the smallest airways of the lungs, the tissue barrier between the lung and the bloodstream and in the pulmonary vasculature; and now also microvascular haemodynamics within the lung, a novel diagnostic approach. The Group will also register and sell the high-performance MRI radiofrequency (RF) coils which are a required component for imaging 129Xe in the MRI system. Providing access to these coils facilitates the adoption of the Xenon technology by providing application-specific RF coils which optimise the imaging of 129Xe in MRI equipment.

The Group was formed on 31 May 2017 when the Company acquired Polarean, Inc (the "Subsidiary"). The Subsidiary was formed as a result of two mergers: the first between Polarean Merger-Sub Inc. and m2m, a company that the Subsidiary had developed a relationship with during the course of previous research and commercialisation programmes in the US and the second between m2m and the Subsidiary. m2m was previously a portfolio company of Amphion Innovations plc ("Amphion"), a developer of medical, life science, and technology businesses, which is itself currently listed on AIM.

#### Investment Case

Pulmonary disease currently affects hundreds of millions of people globally, including approximately 174 million people who suffer from Chronic Obstructive Pulmonary Disease ("COPD"), which is responsible for approximately 6% of such deaths globally each year. In the US more than 30 million people suffer from a chronic lung disease such as COPD, which includes emphysema, chronic bronchitis and asthma. In addition to its significant human toll, pulmonary disease also represents an economic burden in excess of US\$150 billion annually in the US alone.

Every type of pulmonary disease involves some combination of ventilation and/or gas exchange impairment, yet the successful and cost-effective treatment of lung disease is hampered by sub-optimal methods for quantifying pulmonary ventilation and gas exchange. Current diagnostic techniques are either imprecise (such as spirometry) and/or expose the patient to potentially dangerous radiation (such as x-rays, CT scans and nuclear scintigraphy). While spirometry has benefits as a screening tool, none of these current methods can visualise ventilation or gas exchange regionally in the smallest airways, where lung disease typically begins and where improvements from new pharmaceutical therapies can first be detected.

As such, the Group operates in an area of significant unmet medical need and is pursuing approval by the US Food & Drug Administration ("FDA") for the Group's drug-device combination product using hyperpolarised xenon-129 gas to enhance MRI in pulmonary medicine. The Company submitted a new drug application ("NDA") to the FDA on 5 October 2020 after the successful completion of the FDA Phase III clinical trials in the US for the Group's technology. The 80-patient equivalence clinical trials were conducted at Duke University Medical Center, the University of Virginia and The University of Cincinnati three leading US research hospitals. Enrolment of the clinical trials was completed in November 2019. In January 2020, the Company announced that both clinical trials met their primary endpoints, within the prospectively defined equivalence margin (+/-14.7%) when compared to the FDA-approved reference standard, 133Xenon scintigraphy imaging. On 5 October 2021, the Company received a Complete Response Letter ("CRL") from the FDA requesting that the Company to address approvability issues identified by the FDA ahead of NDA resubmission. On 30 March 2022, the Company filed the resubmission of the NDA with the FDA. On 20 April 2022, the Company announced that the FDA had accepted the resubmission of the NDA and established a user fee goal date of 30 September 2022. On 30 September 2022, the Company announced that the FDA had granted the Company a 90 day extension to the NDA review timeline. On 28 December 2022, the Company announced that the FDA had granted approval for its drug device combination product, XENOVIEW. XENOVIEW, prepared from the Xenon Xe 129 Gas Blend, is a hyperpolarised contrast agent indicated for use with magnetic resonance imaging ("MRI") for evaluation of lung ventilation in adults and pediatric patients aged 12 years and older. On 28 December 2022, the Company also announced that, simultaneously with the approval of the XENOVIEW NDA, two 510(k) devices were cleared by the FDA that will further support a successful launch of the technology into the clinical marketplace: XENOVIEW VDP software and the XENOVIEW 3.0T Chest Coil. XENOVIEW VDP is image processing software that analyzes a pulmonary hyperpolarised 129-Xe MR image and a proton chest MR image to provide visualization and evaluation of lung ventilation in adults and pediatric patients aged 12 years and older. This image analysis platform quantifies normalized xenon intensity of a ventilated space using a pulmonary hyperpolarised 129-Xe ventilation MR image and accompanying proton chest MR image. The software will be used by clinicians to assist in the interpretation and numerical classification of hyperpolarized 129-Xe ventilation MR images. The Polarean XENOVIEW 3.0T Chest Coil is a flexible, single channel, transmit-receive (T/R) RF coil tuned to 129Xe frequency on a 3.0T MRI magnetic field of a compatible MRI scanner. The Polarean XENOVIEW 3.0T Chest Coil is indicated to be used in conjunction with compatible 3.0T MRI scanners and approved xenon Xe 129 hyperpolarised for oral inhalation for evaluation of lung ventilation in adults and pediatric patients aged 12 years and older. The Chest Coil is intended to be worn by a patient who inhales hyperpolarised 129Xe gas (XENOVIEW) to obtain an MR image of the regional distribution of hyperpolarised 129Xe in the lungs.

The Group's technology overcomes important limitations of current lung diagnostic methods, providing the ability to visualise, quantify and monitor both the structure and function of the smallest airways and alveolar spaces with enhanced sensitivity and without harmful radiation. This provides a unique, valuable and more precise tool to help diagnose disease earlier, identify the type of intervention likely to benefit a patient, monitor the efficacy of treatment and facilitate developing new therapies for pulmonary diseases.

## **Group Structure and History**

The Company was incorporated in England and Wales on 24 October 2016 with company registration number 10442853. The Company's registered office is 27-28 Eastcastle Street, London, W1W 8DH.

On 31 May 2017, m2m, a company formed in the US State of Delaware on 18 February 1999, was merged into the Company.

On 29 March 2018, the Company's shares were admitted to trading on the AIM market of the London Stock Exchange.

## Information on Polarean, m2m and Strategy of Group

The Subsidiary was co-founded by Dr Bastiaan Driehuys, a current Director of the Company, and John Sudol, a former director of the Subsidiary, in 2011. Prior to co-founding the Subsidiary, Dr Driehuys was a member of a research team at Princeton University in the early 1990s which was amongst the first research teams to focus on hyperpolarised gas MRI technology; in particular isotopically enriched helium (3He). The team developed and held key patents relating to the technology. The technology was acquired in 1999 by Amersham, Inc. ("Amersham"), with the goal of commercialising hyperpolarised helium products to be marketed and distributed alongside Amersham's full line of contrast agent products. Dr Driehuys led the development efforts for Amersham, which continued the development of these hyperpolarised helium products throughout the early 2000s until GE Healthcare ("GE") acquired Amersham in 2004.

GE continued the research and development of hyperpolarised gas MRI after the acquisition of Amersham, focusing on 129Xe as a more effective substitute for 3 He in visualising ventilation. GE also began to explore ways in which 129Xe could be used to image gas exchange within the lung in addition to ventilation. These work programmes culminated in the conduct of a Phase I/II clinical trial at Duke University in 2008-2009. GE also filed Investigational New Drug Applications ('INDs") with the FDA for both 3He and 129Xe. By 2010, after an investment of approximately US\$40 million in the technology and with the regulatory path for hyperpolarised gas remaining unclear, GE decided to out-license the hyperpolarised gas technology and the related patent families that it had developed and/or maintained to the Subsidiary, due to the scale at the time and the early-stage nature of the technology's development.

In December 2011, the Subsidiary negotiated the acquisition of all of GE's assets related to the hyperpolarised MRI project, including an inventory of polarisers and parts and the licenses (or outright ownership) of the related patent families.

Following the acquisition of GE's hyperpolarisation assets, the Subsidiary focused on three key objectives:

- building and selling polarisers to research users to generate operating revenue and to disseminate the technology to academic research institutions that generate clinical data in order to build additional interest in the technology;
- further developing the xenon hyperpolarisation technology in order to meet clinical use specification requirements;
   and
- liaising with the FDA in order to clarify the FDA regulatory path under which the product could achieve clearance to market for clinical use.

In July 2012, the US Congress passed the FDA Safety and Innovation Act and the Medical Gas Act, which clarified and simplified the path under which hyperpolarised gas MRI technology could be approved for clinical use by the FDA.

As a result of discussions between the Group and the FDA, the Directors believed that a clearer path towards regulatory approval existed. As such, following listing our shares on the AIM market the Group began conducting the clinical studies required for FDA approval to market. On 28 December 2022, the Company announced that the FDA had granted approval for its drug device combination product, XENOVIEW. XENOVIEW, prepared from the Xenon Xe 129 Gas Blend, is a hyperpolarised contrast agent indicated for use with MRI for evaluation of lung ventilation in adults and pediatric patients aged 12 years and older.

Between January 2012 and May 2017, the Subsidiary generated over US\$3.7 million of revenue from selling polarisers to customers in Canada, Germany, the UK and the US for research use, relating to both clinical (human) and pre-clinical (animal) applications. In addition, the Subsidiary received additional funding of approximately US\$2.5 million from Nukem and other Series A investors. Prior to the m2m merger, the Subsidiary was also successful in receiving grant funding, including a US\$3 million grant awarded in April 2017 by the US National Heart, Lung and Blood Institute (NHLBI) following a competitive application process (for which the research will be conducted with its clinical collaborator, the Cincinnati Children's Hospital) and a US\$250,000 small business research loan from the North Carolina Biotech Center in March 2017, which was also awarded following a competitive application process.

## 4.2 The Group's Technology and Products

The Subsidiary's lead product has been designated as a drug-device combination by the FDA. The Subsidiary's product enables the visualisation of hyperpolarised <sup>129</sup>Xe ("HPX") through MRI technology to help diagnose lung disease earlier, identify the type of intervention likely to benefit a patient and to monitor the efficacy of treatment. As a result of the FDA's drug-device designation, the Subsidiary's products will be approved and sold only for use with each other. The products are currently being used at a number of research sites on a pre-FDA clearance basis to facilitate the research and evaluation of lung function, to assist in making improved disease progression assessment and to clearly visualise the effectiveness of several therapeutics which are under development. The Group currently generates revenue from the sale of products within its <sup>129</sup>Xe gas hyperpolarisation platform.

Implementing the Group's technology in a clinical setting is straightforward: prior to the MRI scan a patient breathes in a small amount of inert HPX to provide an extremely strong MRI signal. This transforms the MRI from a technology that is not applicable to the lungs into one that is able to provide multiple images of the lung structure and function in one 10-20 second breath-hold. HPX MRI overcomes the limitations of traditional pulmonary function testing as HPX MRI:

- is more accurate and reproducible than spirometry and other traditional pulmonary function tests, enabling the
  detection and mapping of small and localised changes in lung ventilation and gas exchange over time;
- provides regional information about lung disease without exposure to ionising radiation or radioactivity; and
- assesses ventilation and gas exchange in the smallest airways, where disease often begins.

The Group's technology works in conjunction with traditional MRI, transforming it into a powerful diagnostic modality for the lung. The Group's approach is to take 129 Xe, an inert gas, and hyperpolarise the nucleus to create an MRI signal which is approximately 100,000 times stronger than a conventional MRI signal. When the MRI scan is undertaken, the HPX resonates at different frequencies: (i) in the bronchioles and alveoli of the lung; (ii) in the barrier tissue of the lung; and (iii) when dissolved in arterial blood in the pulmonary vasculature, thus providing information on ventilation (the ability of air to reach the alveoli) and gas exchange (the ability of air to diffuse through the alveolar membrane into the pulmonary vasculature). As all pulmonary diseases result from impairments to the free flow of air through bronchioles, or from abnormal gas exchange between the lung alveoli and the pulmonary vasculature, the images that result from HPX MRI scans which have been executed using the Group's technology can aid diagnosis, by enhancing the physician's ability to clearly identify issues with ventilation and gas exchange on a regional basis, down to the smallest of airways. Hyperpolarisation of the 129 Xe is accomplished by placing a non-radioactive isotope of Xenon (129 Xe) into a beam of circularly polarised laser light in the presence of very small concentration of the alkali metal Rubidium, which acts as a physical catalyst in the hyperpolarisation process. The result is 129 Xe whose nuclear magnetic spin is highly aligned but not chemically or biologically different than unpolarised 129 Xe, an inert gas. This hyperpolarised state persists for around 2 hours allowing ample time to administer the HPX to the patient.

The Group's products include:

- the <sup>129</sup>Xe gas, blended and made under GMP at high purity, to be polarised within the polariser;
- the polariser itself, of which the latest model, the Polarean 9820 Xenon Hyperpolariser, has been designed to
  deliver up to 3 litres of HPX per hour (approximately 5-10 doses) of which each dose is to be used within 30
  minutes of its production in order to retain sufficient polarisation to create a strong image;
- the dose delivery inhalation bag, made of HPX-compatible impermeable plastic materials and a mouthpiece for ease of inhalation; and
- the Polarean 2881 Polarisation Measurement Station, which provides a calibrated measurement of the polarisation of hyperpolarised gas within the dose delivery inhalation bag.

The Group currently designs and builds the polariser equipment at a contract manufacturer and has relationships with GMP gas producers to supply the Group with high purity <sup>129</sup>Xe according to the Group's specifications.

In order to take advantage of the Group's current products, an MRI machine is required to be outfitted with hardware and software capable of operating at <sup>129</sup>Xe frequency to detect the HPX signal. In addition, the patient will need to wear a <sup>129</sup>Xe RF chest coil to allow for detecting the HPX MR signal in the lungs. Approximately 35,000 MRI machines are currently in use worldwide and technically many of these can be easily adapted to be used with <sup>129</sup>Xe frequency. The Group's products can be placed near the MRI scanner for ease of radiology workflow and, following the m2m merger, the Group has continued to explore ways to further integrate the Group's existing technology with the coils which had previously been the focus of m2m.

#### 4.3 Location

The Group is based at the Meridian Corporate Center, located in the Research Triangle Park area of North Carolina, which provides a favourable location at which to further develop the core technology and product range. The Group's facilities consist of more than 6,900 square feet of combined offices, laboratory space, inventory warehouse and assembly and testing areas. The Group benefits from facilities that were originally purpose-built by GE for the design and manufacture of hyperpolarisation equipment and components, pursuant to FDA-mandated guidelines.

Within these facilities are a dedicated research and development laboratory equipped with 3-phase power, central compressed air, specialty gas handling and distribution and separate heating, ventilation and air conditioning. The laboratory area also includes optical cell production equipment capable of simultaneous processing of four optical cells for Xenon applications. The laboratory is designed for safe operation of class 4 lasers and is equipped with laser power and spectral testing apparatus.

The Group also maintains a dedicated polariser test bed that is used for product development and a dedicated Nuclear Magnetic Resonance ("NMR") system capable of delivering available electromagnetic field strength, utilised for calibrating absolute polarisation measurements of hyperpolarised gas samples.

# 4.4 The Regulatory Environment

Prior to the receipt of any approvals for clinical use, the Group sold its polarisers and disposables for research use only to academic medical centres with their research being subject to oversight by their respective institutional review boards and conducted under IND from the FDA or equivalent regulatory body.

On 28 December 2022, the Company announced that the FDA had granted approval for its drug device combination product, XENOVIEW. XENOVIEW, prepared from the Xenon Xe 129 Gas Blend, is a hyperpolarised contrast agent indicated for use with MRI for evaluation of lung ventilation in adults and pediatric patients aged 12 years and older.

## 4.5 The Group's Customers

The Group's existing customer base already comprises some of the world's luminary medical imaging research institutions. Indeed, there are numerous research institutions worldwide utilising the Group's system and products, including Cincinnati Children's Hospital, the University of Virginia, University of Wisconsin - Madison, Duke University, University of Kansas, the University of Iowa and the University of Texas MD Anderson Cancer Center in the US, Robarts Research Institute and Hospital for Sick Children (SickKids) in Canada, the University of Oxford and the University of Nottingham in the UK and the Fraunhofer Institute for Toxicology and Experimental Medicine in Germany.

## 4.6 The Group's Suppliers

The Group has entered into Master Service Agreements with two CROs in relation to the Phase III trial. Pharma Start LLC, doing business as Firma Clinical Research, managed the trials and oversaw the recruitment of patients for the trial. In addition, Icon Clinical Research Limited assisted with the medical imaging aspects of the trial.

The Group has a long-standing relationship with its strategic investor Nukem Isotopes GmbH ("Nukem"), a leading global supplier of  $^{129}$ Xe, the isotope of xenon which is provided to the various gas blenders that in turn supply gas to the Group. It has a supply agreement with Nukem for  $^{129}$ Xe.

In June 2020 the Group signed an agreement with Linde Gas North America LLC ("Linde"), in relation to the supply of the Group's drug product, a <sup>129</sup>Xenon gas blend. This agreement contains provision for the supply of bulk <sup>129</sup>Xe to be manufactured into the Active Pharmaceutical Product (API), <sup>129</sup>Xe, and for the blending, packaging, and distribution of its drug product under GMP. On 28 December 2022, the Group signed an amended agreement with Linde, which modified some commercial terms and limited the agreement to the blending packaging and distribution of it drug product under GMP.

The Group has an arrangement with the Blur Product Development ("Blur") to build its polariser systems in Blur's GMP facilities.

## 4.7 Current Trading and Prospects

Trading of the Group since the Company's IPO continues to be in line with the Directors' expectations. The potential of the Group's technology enables the Directors to view the future with confidence as the Company focuses on commercialisation

## 4.8 Growth Strategy

With the recent FDA approval, the Group is adopting a traditional market entry strategy of building market awareness for its technology through key opinion leaders and a direct sales force to reach the key decision makers within its initial target market of large academic medical centres. In implementing this strategy, the Group benefits from approximately 1,000 journal articles on the use of hyperpolarised gas MRI that are currently published in peer-reviewed journals. Over time, as more research centres purchase the Group's equipment and begin clinical studies, an increasing number of peer reviewed scientific articles are likely to be published, further enhancing the Group's credibility and raising awareness of the Group's technology. The Directors believe that the market for polarisers will grow as the technology gains wider acceptance as a tool for studying lung disease and for monitoring the effectiveness of therapeutics. The Group also intends to continue patenting and in-licensing hyperpolarised gas technology IP to protect its current position.

The Group's initial sales targets will be the radiology and pulmonary medicine departments of top academic hospital organisations in the US, who are opinion leaders in the use of new diagnostic technologies and their application in a clinical setting.

The Group is expanding its sales and marketing teams. Because of the specialty nature of the Group's products in the pulmonary specialist market, which is concentrated in approximately 1,000 medical centres, the Directors believe that a small specialty sales force can be deployed effectively at reasonable cost.

The Group may also choose to partner with companies that offer complementary products.

Furthermore, the Directors believe that the Group's products will benefit a number of clinical applications. While the Group's HPX MRI technology provides more specific information than currently available from existing lung diagnostic procedures (especially spirometry), the Group will focus its use on specific clinical conditions where the high accuracy of HPX MRI and greater cost are justified. The Directors do not believe that HPX MRI will replace low-cost spirometry as a general screening tool but believe that it should add value in more demanding clinical applications where HPX MRI addresses unmet diagnostic needs. These applications could include, but are not limited to, the following:

- the monitoring of COPD therapy, especially for the most severe cases;
- the management of cystic fibrosis;
- determining the optimal use of biologic therapy in chronic asthma;
- a more efficient diagnosis of dyspnoea and the chronic cough;
- providing guidance for radiation therapy planning of lung cancer treatment;
- providing guidance for interventional pulmonology procedures including ablation and the placement of valves and stents;
- surgical procedure planning for lung transplant and volume reduction surgery;
- diagnosis of ILD and monitoring of ILD therapy;
- diagnosis of pulmonary vascular disease (PVD) including pulmonary arterial hypertension (PAH) and monitoring of therapy; and
- diagnosis and monitoring of long COVID patients.

The Directors have begun to develop relationships with a range of strategic partners and will evaluate opportunities which will enable the Group to address its target markets globally, either alone or in collaboration with a partner.

## Intellectual Property ("IP")

The Group's technology has been developed in four areas: (i) hyperpolarising gas; (ii) assuring the quality of the hyperpolarised gas; (iii) using the polarised gas in MRI applications; and (iv) developing and producing specialised RF coils to improve signal-to-noise ratios ("SNR"). GE had put a comprehensive patent policy in place to protect its technology from potential competitors. The Group is now the sole owner of this IP portfolio, which is based on 10 patent families, and when combined with the 7 patents that were previously owned by m2m, that were transferred to the Group following the m2m Merger, the Group's portfolio covers four broad types of patents:

- imaging methods these cover the imaging of a subject, or patient, who has inhaled a hyperpolarised noble gas and the functionality of the gas as a contrast agent. Newly licensed technology from Duke University extends the protection over these patents through to the early 2030s;
- hyperpolarisation methods these are polarimetry patents covering the methods by which noble gases are polarised and the methods by which the resulting polarised gas is isolated and delivered to patients. The latest of these patents expire in the early 2020s;
- hyperpolarisation equipment these patents cover the multiple preferred mechanical design and automation elements of hyperpolarised equipment; and
- RF coil patents these patents cover the use of cryogenics to improve RF coils SNR and image quality and may play an
  important part in the next generation of applications such as neurological, cardiac and oncology imaging.

Polarean is committed to proactively developing further IP, both internally and through licensing arrangements with third parties, as part of the Group's overall growth strategy. The third parties are likely to include the Group's key collaborative academic sites, such as Duke University, that are seeking to develop emerging applications and technologies. Because of the Group's extensive patent portfolio and leading market position, the Directors believe the Group is an attractive licensing partner for academic research institutions that are interested in out-licensing such IP. One such patent application (US15/120013), which is currently pending, relates to improving the overall efficiency of the hyperpolarisation process. This patent has also been exclusively licensed to the Group by Duke University. The Directors believe that this patent, now having been prosecuted successfully to issuance in a number of geographic jurisdictions worldwide, would enable the Group to protect methods for increasing the level of hyperpolarisation significantly, which could improve the competitive economics of the Group's products.

## **Principal Risks and Uncertainties**

The principal risks and uncertainties facing the Group are detailed below:

## Early stage of operations

The Group's operations are at an early stage of development and there can be no guarantee that the Group will be able to, or that it will be commercially advantageous for the Group to, develop its proprietary technology. Further, the Group currently has no positive operating cash flow and its ultimate success will depend on the Directors' ability to implement the Group's

strategy, generate cash flow and access capital markets.

#### Principal mitigation

The Group has successfully advanced the <sup>129</sup>Xe technology for several years, including selling polarisers for the research market. The Group has been able to access capital required to continue to advance the technology.

#### Regulatory approvals and compliance

The Group will need to obtain various regulatory approvals (including FDA and European Medicines Agency ("EMA") approvals) and otherwise comply with extensive regulations regarding safety, quality and efficacy standards in order to market its future products. These regulations, including the time required for regulatory review, vary from country to country and can be lengthy, expensive and uncertain.

#### Principal mitigation

The Group utilises external specialists in regulatory affairs who consult with other experts to ensure that internal control processes and clinical trial designs meet current regulatory requirements. The Group also engages directly with regulatory authorities when appropriate.

#### **Future funding requirements**

The Group will need to raise additional funding or enter into a strategic partnership with industry partners to undertake work beyond that being funded by the £27 million (before expenses) 2021 fundraising. There is no certainty that this will be possible at all or on acceptable terms.

#### Principal mitigation

The Group successfully engaged with investors to generate significant cash resources to date, including the 2021 financing that raised £27 million, before expenses. The Group's management team expects that continued access to capital markets, or other access to capital, will be required to support the Group through regulatory approval and initial commercialisation efforts in the US. See Going Concern discussion below.

#### Dependence on key personnel

The success of the Group, in common with other businesses of a similar size, will be highly dependent on the expertise and experience of the Directors and key employees. However, the retention of such key personnel cannot be guaranteed. Should key personnel leave the Group's business, prospects, financial condition or results of operations may be materially adversely affected.

#### Principal mitigation

The Group's recruitment processes are designed to identify and attract the best candidates for specific roles. The Group aims to provide competitive rewards and incentives to staff and directors.

## Intellectual property and proprietary technology

No assurance can be given that any current or future patent applications will result in granted patents, that the scope of any patent protection will exclude competitors or provide competitive advantages to the Group, that any of the Group's patents will be held valid if challenged or that third parties will not claim rights in or ownership of the patents and other proprietary rights held by the Group.

# Principal mitigation

The Group has a long-standing track record of IP generation and successful applications and has a long-standing relationship with our patent attorney who has a deep understanding of our technology. The Group actively manages its IP, engaging with specialists to apply for and defend IP rights in appropriate territories.

## **Technology and products**

The Group is a developer and service provider for noble gas <sup>129</sup>Xe devices and ancillary instruments with a special focus on pulmonary imaging. The development and commercialisation of its proprietary technology and future products, which are in early stages of development, will require multiple series of clinical trials and there is a risk that safety and efficacy issues may arise when the products are tested. There is also a risk that there will be delays to the development of the products or that unforeseen technical problems arise as the Group's technology becomes increasingly automated. These risks are common to all new medical products and there is also a risk that the clinical trials may not be successful.

## Principal mitigation

The Group has a depth of knowledge and experience in the area of medical devices development for the high-resolution medical imaging market. The Group also utilises external experts to supplement their knowledge in critical areas such as safety, manufacturing and software development.

## Research and development risk

The Group will be operating in the life sciences and medical device development sector and will look to exploit opportunities within that sector. The Group will therefore be involved in complex scientific research and industry experience indicates that there may be a very high incidence of delay or failure to produce results. The Group may not be able to develop new products or to identify specific market needs that can be addressed by technology solutions developed by the Group.

## Principal mitigation

The Group has a depth of knowledge and experience in the area of medical devices development for the high-resolution medical imaging market. The Group also utilises external experts to supplement their knowledge in critical areas such as conducting clinical trials and regulatory affairs.

## Competition

The Group notes that several start-ups operating in the CT software space have begun efforts to commercialise products which represent to characterise lung ventilation. These technologies use ionising radiation, whereas the Group's technology does not. In addition, these technologies are unable to further assess gas exchange, red blood cell transport, nor microvascular haemodynamics.

#### Principal mitigation

The Group believes that these emerging technologies validate the unmet need for the use of imaging in assessing pulmonary function. However, their use of ionising radiation, combined with their inability to assess comprehensive pulmonary function will render their utility limited and the Directors see no effect on the current market expectations of Polarean.

#### Reliance on third parties

The business model for the Group anticipates that it will have limited internal resources over the next few years and that it will use third party providers wherever possible to conduct the research, development, registration, manufacture, marketing and sales of its proposed products. The commercial success of the Group's products will depend upon the performance of these third parties.

#### Principal mitigation

The Group seeks experts in the areas where it utilises outsourcing. Wherever possible, the Group seeks to have duplicate suppliers to lessen the reliance on a particular vendor.

#### Manufacturing

There can be no assurance that the Group's proposed products will be capable of being manufactured in commercial quantities, in compliance with regulatory requirements and at an acceptable cost. The Group outsources the manufacture of the raw materials and finished products required in connection with the research, development and commercial manufacture of its proposed products and, as such, is wholly dependent upon third parties for the provision of adequate facilities and raw material supplies. <sup>129</sup>Xe, the specific isotope of xenon which is the active ingredient in the Group's drugdevice product, is available from a limited number of suppliers and there can be no assurance that adequate supplies of this material at acceptable cost can be obtained. In addition, where the Group is dependent upon third parties for manufacture, its ability to procure the manufacture of the drug-device in a manner which complies with regulatory requirements may be constrained, and its ability to develop and deliver such products on a timely and competitive basis may be adversely affected.

#### Principal mitigation

The Group has designed the manufacturing process to be scalable and has internal experts who train the outside vendors. The Group has established relationships with two  $^{129}$ Xe suppliers to mitigate the risk that  $^{129}$ Xe supply will be a limitation to the development and commercialisation of its products. In addition, the Group has established a relationship with a GMP outside polariser manufacturer.

## Product development timelines

Product development timelines are at risk of delay, particularly since it is not always possible to predict what the FDA will require for approval of future NDA's. There is a risk therefore that product development could take longer than presently expected by the Directors. If such delays occur the Group may require further working capital. The Directors shall seek to minimise the risk of delays by careful management of projects.

## Principal mitigation

The Group utilises consultants who are experts in preparing and filing future NDAs in the US.

## General legal and regulatory issues

The Group's operations are subject to laws, regulatory restrictions and certain governmental directives, recommendations and guidelines relating to, amongst other things, occupational safety, laboratory practice, the use and handling of hazardous materials, prevention of illness and injury, environmental protection and animal and human testing. There can be no assurance that future legislation will not impose further government regulation, which may adversely affect the business or financial condition of the Group.

## Principal mitigation

The Group consults experts for advice in areas such as occupational safety, laboratory practice and human testing.

# Healthcare pricing environment

In common with other healthcare products companies, the ability of the Group and any of its licensees or collaborators to market its products successfully depends in part on the extent to which reimbursement for the cost of such products and related treatment will be available from government health administration authorities, private health coverage insurers and other organisations.

## Principal mitigation

The Group is consulting with several experts in the field of reimbursement for healthcare products in the US to determine the best strategy for accessing adequate reimbursement for its products.

## Section 172 statement

As required by section 172 of the Companies Act 2006 (the "Act"), a director of a company must act in the way he or she considers, in good faith, would likely promote the success of the company for the benefit of the shareholders. In doing so, the director must have regard amongst other matters to the following issues:

un ector must have regard, amongst other matters, to the following issues.

- $\bullet$  the likely consequences of any decisions in the long term;
- $\bullet$  the interests of the company's employees;
- the need to foster the company's business relationships with suppliers/customers and others;
- the impact of the company's operations on the community and environment;
- the company's reputation for high standards of business conduct; and
- the need to act fairly between members of the company.

The information required by section 172 of the Act is included in the full Annual Report.

## Kenneth West Non-Executive Chairman 25 May 2023

## **Consolidated Statement of Comprehensive Income**

		2022	2021
	Notes	US\$	US\$
Revenue	4	1,033,008	1,185,427
Cost of sales		(684,732)	(677,402)
Gross profit		348,276	508,025
Administrative expenses		(8,464,766)	(6,517,396)
Depreciation	11	(277,461)	(177,349)
Amortisation	6	(760,780)	(757,016)
Selling and distribution expenses		(3,310,592)	(5,557,829)
Share-based payment expense	19	(1,205,247)	(1,814,882)
Total operating costs		(14,018,846)	(14,824,472)
Operating loss	6	(13,670,570)	(14,316,447)
Finance income	7	35,045	2,587
Finance expense	7	(23,762)	(21,101)
Other gains/(losses) - net	7	(246,309)	318,957
Loss before tax		(13,905,596)	(14,016,004)
Taxation	10	<u>-</u>	
Loss for the year and total other comprehensive expense		(13,905,596)	(14,016,004)
Loss per share			
Basic and diluted (US\$)	9	(0.066)	(0.071)

The results reflected above relate to continuing activities.

There are no items of Other Comprehensive Income ("OCI") for the year other than the loss above and therefore no separate statement of other comprehensive income has been presented.

## **Consolidated Statement of Financial Position**

	Notes	2022	2021
		US\$	US\$
ASSETS			
Non-current assets			
Property, plant and equipment	11	418,498	634,779
Intangible assets	12	1,581,591	2,193,843
Right-of-use assets	24	274,288	422,816
Trade and other receivables	14	437,539	5,539
		2,711,916	3,256,977
Current assets			
Inventories	15	1,711,419	1,426,810
Trade and other receivables	14	1,659,649	970,968
Cash and cash equivalents	16	16,454,241	28,874,908
		19,825,309	31,272,686
TOTAL ASSETS		22,537,225	34,529,663
EQUITY AND LIABILITIES			
Equity attributable to holders of the parent			
Share capital	17	103,463	101,642
Share premium	18	59,288,383	59,022,919
Group re-organisation reserve	18	7,813,337	7,813,337
Share-based payment reserve	19	4,865,579	3,660,332
Accumulated losses	18	(52,765,804)	(38,860,208)
		19,304,958	31,738,022
Non-current liabilities			
Deferred income	21	128,704	145,747
Trade and other payables	22	360,000	-
Lease liability	24	216,691	358,837
Contingent consideration	20	316,000	316,000
	•	1,021,395	820,584
Current liabilities			
Trade and other payables	22	1,979,001	1,731,114
Lease liability	24	142,146	130,949
Deferred income	21	89,725	108,994
	•	2,210,872	1,971,057
TOTAL EQUITY AND LIABILITIES	•	22,537,225	34,529,663
	•		

These Financial Statements were approved and authorised for issue by the Board of Directors on 25 May 2023 and were signed on its behalf by:

Kenneth West Non-Executive Chairman

Company number: 10442853

# **Consolidated Statement of Changes in Equity**

	Share capital US\$	Share premium US\$	Share-based payment reserve US\$	Group re-organisation reserve US\$
As at 1 January 2021	78,200	23,840,571	1,845,450	7,813,337
Comprehensive income				
Loss for the year	-	-	-	-
Transactions with owners				
Issue of shares	23,442	37,284,454	-	-
Share issue costs	-	(2.102.106)	-	-

Share-based payment expense			1,814,882	
As at 31 December 2021 (audited)	101,642	59,022,919	3,660,332	7,813,337
Comprehensive income				
Loss for the year	-	-	-	-
Transactions with owners				
Issue of shares	1,821	265,464	-	-
Share-based payment expense			1,205,247	
As at 31 December 2022	103,463	59,288,383	4,865,579	7,813,337

# Consolidated Statement of Cash Flows

	2022 US\$	2021 US\$
Cash flows from operating activities		
Loss before tax	(13,905,596)	(14,016,004)
Adjustments for non-cash/non-operating items:		
Depreciation of property, plant and equipment	277,461	177,349
Amortisation of intangible assets and right-of use-assets	760,780	757,015
Loss on disposal of property, plant and equipment	2,766	590
Loss on remeasurement of right-of-use assets	-	11,660
Share-based payment expense	1,205,247	1,814,882
Net foreign exchange losses/(gains)	246,309	(318,957)
Finance expense	23,762	21,101
Finance income	(35,045)	(2,587)
Operating cash outflows before movements in working capital	(11,424,316)	(11,554,951)
Increase in inventories	(284,609)	(448,886)
Increase in trade and other receivables	(1,120,681)	(622,901)
Increase in trade and other payables	607,887	382,247
Decrease in deferred income	(36,312)	(5,976)
Net cash used in operations	(12,258,031)	(12,250,467)
Cash flows from investing activities		
Purchase of property, plant and equipment	(63,946)	(541,454)
Net cash used in investing activities	(63,946)	(541,454)
Cash flows from financing activities		
Issue of shares	267,285	37,307,896
Cost of issue	-	(2,102,106)
Interest paid on lease liabilities	(23,762)	(21,101)
Interest received	35,045	2,587
Principal elements of lease payments	(130,949)	(122,069)
		35,065,207
Net cash generated by financing activities	147,619	
Net (decrease)/increase in cash and cash equivalents	(12,174,358)	22,273,286
Cash and cash equivalents at the beginning of year	28,874,908	6,282,665
Effect of foreign exchange rate changes on cash and cash equivalents	(246,309)	318,957
Cash and cash equivalents at end of year	16,454,241	28,874,908

# Notes to the Financial Statements

# General information

10442853 and its registered office is at 27-28 Eastcastle Street, London, W1W 8DH.The Company is listed on the AIM market of the London Stock Exchange.

The Company is the parent company of Polarean, Inc (the "Subsidiary", together the "Group"). The principal activity of the Group is developing next generation medical imaging technology. The Subsidiary is incorporated in the United States of America and has a registered office of 2500 Meridian Parkway #175, Durham, NC 27713, USA.

## Adoption of new and revised International Financial Reporting Standards

#### Standards and interpretations adopted during the year

Information on new standards, amendments and interpretations that are relevant to the Group's annual report and accounts is provided below:

- Onerous Contracts Cost of Fulfilling a Contract (Amendments to IAS 37);
- Property, Plant and Equipment: Proceeds before Intended Use (Amendments to IAS 16);
- Annual Improvements to IFRS Standards 2018-2020 (Amendments to IFRS 1, IFRS 9, IFRS 16 and IAS 41);
   and
- References to Conceptual Framework (Amendments to IFRS 3).

These standards have no material impact on the Group.

#### Standards, amendments and interpretations that are not yet effective

There are a number of standards, amendments to standards, and interpretations which have been issued by the United Kingdom Endorsement Board (UKEB) that are effective in future accounting periods that the Company has decided not to adopt early. These standards, amendments or interpretations are not expected to have a material impact on the Group.

#### Significant accounting policies

#### Basis of preparation

These financial statements have been prepared in accordance with UK adopted International Accounting Standards ("IFRS") and under the historical cost convention. The financial statements are presented in United States Dollars ("US\$") except where otherwise indicated.

The principal accounting policies adopted in the preparation of the financial statements are set out below. The policies have been consistently applied to all the years presented, unless otherwise stated.

## Going concern

The Group is moving from the development stage to full commercial exploitation of its IP. During the year ended 31 December 2022 the Group recorded a loss after tax of US\$13,905,596 (2021: loss of US\$14,016,004) and a net cash outflow from operating activities of US\$12,258,031 (2021: US\$12,250,467).

The Directors have prepared financial projections and plans for a period of at least 12 months from the date of approval of these financial statements. Based on the current management plan, management believes that these funds are sufficient for the expenditure to date as well as the planned forecast expenditure for the forthcoming 12 months.

It is anticipated that additional capital will need to be raised by the end of the second quarter of 2024 in order to continue to fund the Group's activities at their planned levels beyond this date. This represents a material uncertainty that may cast significant doubt about the Group's and Company's ability to continue as a going concern. However, the Directors have a reasonable expectation that this uncertainty can be managed to a successful outcome, and based on that assessment, the Group and Company will have adequate resources to continue in operational existence for the foreseeable future. Accordingly, these financial statements have been prepared on the going concern basis.

The financial statements do not reflect any adjustments that would be required to be made if they were to be prepared on a basis other than the going concern basis.

## Share capital

Ordinary shares are classified as equity. Incremental costs directly attributable to the issue of new shares are shown in share premium as a deduction from the proceeds.

## Inventory

Inventories are measured at the lower of cost and net realisable value. The cost of inventories is based on the weighted average cost principle and includes expenditure incurred in inventories, adjusted for rebates, and other costs incurred in bringing them to their existing location.

## Cash and cash equivalents

 $Cash\ and\ cash\ equivalents\ comprise\ cash\ balances\ and\ call\ deposits\ with\ an\ original\ maturity\ of\ three\ months\ or\ less.$ 

# Functional and presentation currency

Items included in the financial statements of the Group are measured using the currency of the primary economic environment in which the Group operates ("the functional currency"). The financial statements are presented in United States Dollars (US\$) which is also the Group's functional currency.

Transactions in foreign currencies are initially recorded by the Group's entities at their respective functional currency spot rates at the date the transaction first qualifies for recognition.

Monetary assets and liabilities denominated in foreign currencies are translated at the functional currency spot rates of exchange at the reporting date.

Differences arising on settlement or translation of monetary items are recognised in profit or loss.

For the purpose of presenting the consolidated financial statements, the assets and liabilities of the Group's foreign operations are translated at exchange rates prevailing on the reporting date. Income and expense items are translated at the average exchange rates for each period, unless exchange rates fluctuate significantly during that period, in which case the exchange rates at the date of transaction are used. All resulting exchange differences are recognised in "other comprehensive income" and accumulated in equity.

#### Basis of consolidation

The consolidated financial statements are for the year ended 31 December 2022. The measurement bases and principal accounting policies of the Group are set out below.

On 30 May 2017 Polarean Merger-Sub, Inc., a Subsidiary of the Subsidiary, completed a merger process under which it acquired substantially all of the assets of m2m Imaging Corp ("m2m"), a portfolio company of Amphion Innovations plc engaged in the development of high-performance MRI RF coils for the global research market, primarily in micro-imaging. By 2016 m2m had been inactive for several years due to an inability to raise funds. At the date of the merger the assets of m2m were its technology and patents. The merger was affected by way of court sanction in the process of which the Subsidiary acquired, through a special purpose entity, Polarean Merger Sub, Inc. the assets of another special purpose entity, m2m Merger Sub, Inc., with m2m Merger Sub, Inc. being the surviving entity. After the reporting date, on 1 September 2017, m2m Merger Sub, Inc. was merged into the Subsidiary with the Subsidiary being the surviving entity, the effect being that m2m Merger Sub, Inc. was collapsed, and the Subsidiary had acquired the m2m assets.

As part of the arrangements for the merger 576,430 shares in the Subsidiary were issued to the former shareholders in m2m with the intention that all parties would exchange their stock in Polarean, Inc. for shares in the Group on a pro rata basis as soon as practicable.

The Directors consider the merger between the Subsidiary and m2m Acquisition, Inc. as a consequence of which the group acquired the exclusive worldwide rights to m2m's technology and patents does not meet the definition of an acquisition of a business as set out in IFRS3 and has therefore been accounted for as the acquisition of an asset or a group of assets that does not constitute a business.

IFRS 3 requires that in such cases the acquirer shall identify and recognise the individual identifiable assets acquired (including those assets that meet the definition of, and recognition criteria for, intangible assets in IAS 38 Intangible assets) and to allocate the cost of the individual identifiable assets and liabilities on the basis of their relative fair values at the date of purchase. Such a transaction or event does not give rise to goodwill.

The fair value of the assets acquired under the merger arrangement of US\$4,999,996 represents the aggregate estimated value of the financial obligations of the former m2m shareholders which were converted into equity in m2m prior to the merger agreement.

The Directors consider the acquisition of the entire issued common stock of the Subsidiary by the Company in exchange for equivalent equity participation in the Company to be a group re-organisation and not a business combination and to fall outside the scope of IFRS 3. Having considered the requirements of IAS 8 and the relevant UK and US guidance, the transaction has been accounted for on a merger or pooling of interest basis as if both entities had always been combined, using book values, with no fair value adjustments made nor goodwill recognised.

# Revenue recognition

Revenue comprises the fair value of the sale of goods and rendering of services to external customers, net of applicable sales tax, rebates, promotions and returns.

## Contracts and obligation

The majority of customer contracts have three main elements that the Group provides to the customer:

- Sale of polarisers;
- Sale of parts and upgrades; and
- Provision of service.

The sale of polarisers is seen as a distinct performance obligation and revenue is recognised at a point in time. The customer can benefit from the use of the polarisers when supplied and is not reliant on the Group to provide the parts and upgrades or service, and therefore revenue from the sale of polarisers is recognised in full when the goods are delivered to the customer.

The second performance obligation is the sale of parts and upgrades. The customer can benefit from the use of the parts and upgrade when supplied and is not reliant on the Group to provide the service, and therefore revenue from the sale of parts and upgrades is recognised in full when the goods are delivered to the customer.

The third performance obligation is the provision of preventive maintenance service. Revenue from the provision of preventive maintenance service is recognised over the period when the services are rendered. A contract liability represents the obligation of the Group to render services to a customer for which consideration has been received (or the amount is due) from the customer.

## Determining the transaction price

The transaction price is determined as the fair value of the Group expects to receive over the course of the contract.

There are no incentives given to customers that would have a material effect on the financial statements.

#### Allocate the transaction price to the performance obligations in the contract

The allocation of the transaction price to the performance obligations in the contract is non-complex for the Group. There is a fixed unit price for each product or service sold. Therefore, there is limited judgement involved in allocating the contract price to each unit ordered.

## Recognise revenue when or as the entity satisfies its performance obligations

The overarching terms are consistent in each contract.

The sale of polarisers is seen as a distinct performance obligation and revenue is recognised at a point in time, when title of the goods transferred to the customer, as the customer can benefit from the use of the polarisers when supplied.

The sale of parts and upgrades is seen as a distinct performance obligation and revenue is recognised at a point in time, when supplied to the customer, as the customer can benefit from the use of the parts and upgrade when supplied.

The provision of service is seen as a distinct performance obligation and revenue is recognised as the Group provides these services for the duration of the contract, i.e. over time. Any unexpired portion of a service contract or payment received in advance in respect of service contracts either partially completed or not started, are included in deferred income and released over their remaining term.

## Property, plant and equipment

#### Owned assets

Items of property, plant and equipment are stated at cost or deemed cost less accumulated depreciation and impairment losses. Cost includes the original purchase price of the asset and the costs attributable to bringing the asset to its working condition for its intended use. When parts of an item of property, plant and equipment have different useful lives, those components are accounted for as separate items of property, plant and equipment.

Subsequent costs are included in the asset's carrying amount or recognised as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Group and the cost of the item can be measured reliably.

#### Depreciation

Depreciation is charged to profit or loss on a straight-line basis over the estimated useful lives of each part of an item of property, plant and equipment. The estimated useful lives are as follows:

- Computer and IT equipment 33% straight line
- Leasehold improvements 20% straight line
- Laboratory equipment 20% straight line

The residual values, useful lives and depreciation methods are reviewed, and adjusted if appropriate, or if there is an indication of a significant change since the last reporting date.

Gains and losses on disposals are determined by comparing the proceeds with the carrying amount and are recognised within administrative expenses in the statement of comprehensive income.

# Intangible Assets

Patents and related rights are assessed by reviewing their net present value of future cash flows. Patents are currently amortised over their useful life, not exceeding 10 years.

Internally generated intangible assets - research costs are costs incurred in research activities and are recognised as an expense in the period in which they are incurred. An internally generated intangible asset arising from the development of commercial technologies is recognised only if all of the following conditions are met:

- it is probable that the asset will create future economic benefits;
- the development costs can be measured reliably;
- technical feasibility of completing the intangible asset can be demonstrated;
- there is the intention to complete the asset and use or sell it;
- there is the ability to use or sell the asset; and
- adequate technical, financial and other resources to complete the development and to use or sell the asset are available.

At this time the Directors consider that the Group does not meet all of those conditions and development costs are therefore recorded as expense in the period in which the cost is incurred.

## Impairment of non-financial assets

Non-financial assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognised for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs to sell and value in use. For the purposes of assessing impairment, assets are reviewed at the lowest levels for which there are separately identifiable cash flows (cash-generating units).

Non-financial assets other than goodwill that suffered impairment are reviewed for possible reversal of the impairment at each reporting date.

A provision is recognised in the statement of financial position when the Group has a present legal or constructive obligation as a result of a past event, and it is probable that an outflow of economic benefits will be required to settle the obligation. If the effect is material, provisions are determined by discounting the expected future cash flows at a pre-tax rate that reflects current market assessments of the time value of money and, when appropriate, the risks specific to the liability. The increase in the provision due to the passage of time is recognised in finance costs.

#### Financial assets

The Group classifies all of its financial assets at amortised cost. Financial assets do not comprise prepayments. Management determines the classification of its financial assets at initial recognition.

These assets arise principally from the provision of goods and services to customers (e.g. trade receivables), but also incorporate other types of financial assets where the objective is to hold their assets in order to collect contractual cash flows and the contractual cash flows are solely payments of the principal and interest. They are initially recognised at fair value plus transaction costs that are directly attributable to their acquisition or issue and are subsequently carried at amortised cost using the effective interest rate method, less provision for impairment.

#### **Amortised Cost**

The Group's financial assets held at amortised cost comprise trade and other receivables and cash and cash equivalents in the consolidated statement of financial position.

Impairment provisions for trade receivables are recognised based on the simplified approach within IFRS 9 using the lifetime expected credit losses. During this process the probability of the non-payment of the trade receivables is assessed. This probability is then multiplied by the amount of the expected loss arising from default to determine the lifetime expected credit loss for the trade receivables. For trade receivables, which are reported net; such provisions are recorded in a separate provision account with the loss being recognised within administrative expenses in the consolidated statement of comprehensive income. On confirmation that the trade receivable will not be collectable, the gross carrying value of the asset is written off against the associated provision.

Impairment provisions for other receivables are recognised based on the general impairment model within IFRS 9. In doing so, the Company follows the 3-stage approach to expected credit losses. Step 1 is to estimate the probability that the debtor will default over the next 12 months. Step 2 considers if the credit risk has increased significantly since initial recognition of the debtor. Finally, Step 3 considers if the debtor is credit impaired, following the criteria under IAS 39.

#### Financial liabilities

The Group classifies its financial liabilities in the category of financial liabilities at amortised cost. All financial liabilities are recognised in the statement of financial position when the Group becomes a party to the contractual provision of the instrument.

Financial liabilities measured at amortised cost comprise trade payables and other short-dated monetary liabilities, which are initially recognised at fair value and subsequently carried at amortised cost using the effective interest rate method.

Unless otherwise indicated, the carrying values of the Group's financial liabilities measured at amortised cost represents a reasonable approximation of their fair values.

## Employee benefits: pension obligations

The Group operates a defined contribution plan. A defined contribution plan is a pension plan under which the Group pays fixed contributions into a separate entity. The Group has no legal or constructive obligations to pay further contributions if the fund does not hold sufficient assets to pay all employees the benefits relating to employee service in the current and prior periods.

The Group has no further payment obligations once the contributions have been paid. The contributions are recognised as employee benefit expense when they are due. Prepaid contributions are recognised as an asset to the extent that a cash refund or a reduction in the future payments is available.

## Finance costs

Finance costs comprise interest on lease liabilities; and are expensed using the effective interest method in the period in which they are incurred.

## Finance income

Finance income comprises interest income and dividend income.

Interest income is recognised in the income statement as it accrues using the effective interest method.

## Other gains and losses - net

 $Other\ gains\ and\ losses\ comprise\ for eign\ exchange\ gains\ and\ losses\ on\ cash\ and\ cash\ equivalents.$ 

## Leases

# Definition of a lease

The Group assesses whether a contract is or contains a lease. A contract is or contains a lease if the contract conveys a right to control the use of an identified asset for a period of time in exchange for consideration.

The Group recognises a right-of-use asset and a lease liability at the lease commencement date. The right-of-use asset is initially measured at cost, and subsequently at cost less any accumulated amortisation and impairment

losses and adjusted for certain measurements of the lease liability. Right-of-use assets are amortised on a straight-line basis over the remaining term of the lease or over the remaining economic life of the asset if, rarely, this is judged to be shorter than the lease term.

The lease liability is initially measured at the present value of the lease payments that are not paid at the commencement date, discounted using the interest rate implicit or, if that rate cannot be readily determined, the Group's incremental borrowing rate. Generally, the Group uses its incremental borrowing rate as the discount rate.

The lease liability is subsequently increased by the interest cost on the lease liability and decreased by lease payments made. It is remeasured when there is a change in future lease payments arising from a change in an index or rate, a change in estimate of the amount expected to be payable under a residual value guarantee, or as appropriate, changes in the assessment of whether a purchase or extension option is reasonably certain to be exercised or a termination option is reasonably certain not to be exercised.

The Group has applied judgement to determine the lease term for some lease contracts in which it is a lease that include renewal options. The assessment of whether the Group is reasonably certain to exercise such options impacts the lease term, which significantly affects the amount of lease liabilities ad right-of-use assets recognised.

As at 31 December 2022, potential future cash outflows of \$479,477 (undiscounted) have not been included in the lease liability because it is not reasonably certain that the leases will be extended (2021: \$421,142).

#### Income tax

Income tax for the years presented comprises current and deferred tax. Income tax is recognised in the income statement except to the extent that it relates to items recognised directly in equity, in which case it is recognised in equity. Current tax is the expected tax payable on the taxable income for the year, using tax rates enacted or substantively enacted at the statement of financial position date, and any adjustment to tax payable in respect of previous years.

Deferred tax is recognised on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts.

The following temporary differences are not recognised if they arise from a) the initial recognition of goodwill, and b) for the initial recognition of other assets or liabilities in a transaction other than a business combination that at the time of the transaction affects neither accounting nor taxable profit or loss. Deferred tax is determined using tax rates and laws that have been enacted or substantially enacted by the balance sheet date and are expected to apply when the related deferred tax asset is realised, or the deferred income tax liability is settled.

A deferred tax asset is recognised only to the extent that it is probable that future taxable profits will be available against which the asset can be utilised. Deferred tax assets are reduced to the extent that it is no longer probable that the related tax benefit will be realised.

Deferred income tax assets and liabilities are offset when there is a legally enforceable right to offset current tax assets against current tax liabilities and when the deferred income taxes assets and liabilities relate to income taxes levied by the same taxation authority on either the taxable entity or different taxable entities where there is an intention to settle the balances on a net basis.

## Critical accounting estimates and judgements

The preparation of the Group's financial statements under IFRS requires the directors to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities. 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. Actual results may differ from these estimates.

The directors consider that the following judgements are likely to have the most significant effect on the amounts recognised in the financial statements.

## Carrying value of intangible assets - Group

In determining whether there are indicators of impairment of the Group's intangible assets, the directors take into consideration various factors including the economic viability and expected future financial performance of the asset and when it relates to the intangible assets arising on a business combination, the expected future performance of the business acquired.

# Carrying value of investments in and amounts receivable from subsidiaries - Company

In determining whether there are indicators of impairment of the Company's investments in, and amounts receivable from, its subsidiary undertakings, the directors take into consideration various factors including the economic viability and expected future financial performance of the business of the subsidiary undertakings.

# 4. Segmental information

IFRS 8 requires operating segments to be identified on the basis of internal reports about components of the Group that are regularly reviewed by the chief operating decision maker (which takes the form of the Board of Directors) as defined in IFRS 8, in order to allocate resources to the segment and to assess its performance.

The chief operating decision maker has determined that the Group has one operating segment, the development and commercialisation of gas polariser devices and ancillary instruments. Revenues are reviewed based on the products and services provided: Polarisers, Parts and Upgrades, Service and Other revenue.

The Group trades in Canada, Germany, the United Kingdom and the United States of America. Revenue by origin of geographical segment for all entities in the Group is as follows:

Revenue		
	2022	2021
	US\$	US\$
Canada	446,396	529,824
Germany	-	6,750
United Kingdom	17,800	25,183
United States of America	568,812	623,670
Total	1,033,008	1,185,427
Non-current assets		
Non-current ussets	2022	2021
	US\$	US\$
United States of America	2,711,916	3,256,977
Total	2,711,916	3,256,977
Product and services revenue analysis		
Revenue		
	2022	2021
	US\$	US\$
Polarisers	759,099	826,059
Parts and Upgrades	155,787	275,789
Service	118,122	83,579
Total	1,033,008	1,185,427

Management measures revenues by reference to the Group's core services and products and related services, which underpin such income.

# 5. Employees and Directors

Staff costs for the Group and the Company during the year:		
	2022	2021
	US\$	US\$
Wages and salaries	4,207,833	3,604,758
Healthcare benefits	248,927	220,476
Social Security costs	290,531	248,063
=	4,747,341	4,073,297
Average monthly number of people (including directors) employed by activity	<i>r</i> :	
	2022	2021
	No.	No.
Senior management including directors	11	10
R&D and clinical trial	10	11
Administration	7	7
Total _	28	28
Key management compensation:		
The following table details the aggregate compensation paid to key managem	ent personnel.	
	2022	2021
	US\$	US\$
Salaries and fees	1,527,810	1,394,235
Healthcare benefits	85,025	85,830
Social security costs	70,311	69,465
_	1,683,146	1,549,530

Key management personnel include all directors who together have authority and responsibility for planning, directing, and controlling the activities of the Group and senior divisional managers.

# 6. Operating loss

	2022	2021
	US\$	US\$
Depreciation		
<ul> <li>Owned property, plant and equipment</li> </ul>	277,461	177,349
Amortisation of right-of-use assets	148.528	140.164

	1.0,010	,
Amortisation of intangible assets	612,252	616,851
Subtotal Amortisation	760,780	757,015
Research expenses	619,007	649,695
Auditors' remuneration (note 8)	66,000	55,664
Clinical trial costs	1,070,004	(52,599)
Regulatory consulting costs	1,964,040	1,126,675
Legal and professional fees	493,290	494,688
Brand development and market research	134,645	2,091,921
Medical affairs and congress/symposia	353,066	916,238
7. Other income and expense items		
	2022	2021
	US\$	US\$
Finance income		
Sundry income	35,045	2,587
Total finance income	35,045	2,587
Finance expense		
Interest on lease liabilities	23,762	21,101
Total finance expense	23,762	21,101
	2022	2021
Other gains and losses - net	US\$	US\$
Foreign exchange gains/(losses)	(246,309) (246,309)	318,957 318,957
8. Auditor remuneration		
	2025	2654
	2022	2021
A No. 1	US\$	US\$
Auditors' remuneration Fees payable to the Group's auditor for audit of Parent Company and		
Consolidated Financial Statements	66,000	55,664
		,

# 9. Loss per share

The loss per share has been calculated using the loss for the year and the weighted average number of ordinary shares outstanding during the year, as follows:

	2022 US\$	2021 US\$
Loss for the year attributable to shareholders of the Group (US\$) Weighted average number of ordinary shares	(13,905,596) 211,948,868	(14,016,004) 196,961,274
Basic and diluted loss per share	(0.066)	(0.071)

For diluted loss per share, the weighted average number of ordinary shares in issue is adjusted to assume conversion of all potential dilutive warrants, options and convertible loans over ordinary shares. Potential ordinary shares resulting from the exercise of warrants, options and the conversion of convertible loans have an anti-dilutive effect due to the Group being in a loss position. As a result, diluted loss per share is disclosed as the same value as basic loss per share.

## 10. Taxation

There were no charges to income tax due to the losses incurred by the Group in the period.

Income taxes computed at the statutory federal income tax of 21% (2021: 21%) and the state income tax of 2.5% (2021: 2.50%) UK corporation tax is calculated at 19% of the estimated assessable profits for the year.

	2022	2021
	US\$	US\$
Loss on ordinary activities before tax	(13,905,596)	(14,016,004)
Taxable permanent differences	(254,993)	(49,828)
Taxable loss on ordinary activities	(14,160,589)	(14,065,832)
Taxable loss on ordinary activities multiplied by the rate of corporation tax in the US as above	(2,973,724)	(2,953,825)
Effects of:		
Adjustments for rate of tax in other jurisdictions	40,752	42,577
Unrelieved tax losses carried forward	2,932,971	2,911,248
Total taxation charge	-	

The tax reform act of 1986 contains provisions which limit the ability to utilise the net operating loss carry

forwards in the case of certain events including significant changes in ownership interests. If the Group's net operating loss carried forward, the Group would incur a federal income tax liability even though net operating loss carry forwards would be available in future years.

The Group has tax losses carried forward of US\$47,297,438 (2021: US\$33,391,842). The unutilised tax losses have not been recognised as a deferred tax asset due to uncertainty over the timing of future profits and gains. In addition, there are approximately US\$726,000 (2021: US\$531,000) of unrecognised deferred tax assets in respect of the share-based payment.

## 11. Property, plant and equipment

	Leasehold	Furniture and	Computers and	
	improvements	equipment	IT equipment	Total
	US\$	US\$	US\$	US\$
Cost				
At 1 January 2021	13,658	440,790	59,273	513,721
Additions	17,050	464,585	59,819	541,454
Disposals	-	-	(1,328)	(1,328)
At 31 December 2021	30,708	905,375	117,764	1,053,847
Additions	3,500	52,470	7,976	63,946
Disposals	-	-	(5,298)	(5,298)
At 31 December 2022	34,208	957,845	120,442	1,112,495
Accumulated depreciation				
At 1 January 2021	6,068	213,012	23,377	242,457
Depreciation expense	7,934	146,656	22,759	177,349
Disposals	-	-	(738)	(738)
At 31 December 2021	14,002	359,668	45,398	419,068
Depreciation expense	5,864	237,778	33,819	277,461
Disposals	-	-	(2,532)	(2,532)
At 31 December 2022	19,866	597,446	76,685	693,997
Carrying amount				
At 31 December 2021	16,706	545,707	72,366	634,779
At 31 December 2022	14,342	360,399	43,757	418,498

12	Intangible assets
IZ.	Intangible assets

	Patents	Total
	US\$	US\$
Cost		
At 1 January 2021	5,045,996	5,045,996
Additions	-	-
At 31 December 2021	5,045,996	5,045,996
Additions	=	=
At 31 December 2022	5,045,996	5,045,996
Accumulated amortisation	<u> </u>	
At 1 January 2021	2,235,302	2,235,302
Amortisation expense	616,851	616,851
At 31 December 2021	2,852,153	2,852,153
Amortisation expense	612,252	612,252
At 31 December 2022	3,464,405	3,464,405
Carrying amount		
At 31 December 2021	2,193,843	2,193,843
At 31 December 2022	1,581,591	1,581,591

# 13. Investment in subsidiary undertaking

Company Cost	Investment in subsidiary undertaking US\$	Amount due from subsidiary undertaking US\$	Total US\$
At 31 December 2021	4,342,848	53,837,466	58,180,314
At 31 December 2022	4,342,848	54,019,443	58,362,291
Carrying amount			
At 31 December 2021	4,342,848	53,837,466	58,180,314
At 31 December 2022	4,342,848	54,019,443	58,362,291

The investment in subsidiary undertaking is stated at cost less provision for impairment. The amount due from

subsidiary undertaking are regarded as net investment which is subject to the impairment assessment whenever events or changes in circumstance indicate that the carrying value of the investment and the amount due from subsidiary undertakings may not be recoverable. For the year under review, there is no such indicator for impairment.

The net carrying amounts noted above relates to the Subsidiary. The subsidiary undertaking during the year were

	Registered office address	Country of incorporation	Interest held %
Polarean Inc.	2500 Meridian Parkway #175, Durham, NC 27713, USA	USA	100

14. Trade and other rece	eivables						
			Group		Ca	mpany	
Amounts falling due after	one year	2022		2021	2022		2021
, , ,	·	US\$		US\$	US\$		US\$
Rental deposit		5,539		5,539	-		-
Prepayments		432,000		-	-		-
		437,539		5,539	-		-
			Group		Ca	mpany	
Amounts falling due within	n one year	2022		2021	2022		2021
		US\$		US\$	US\$		US\$
Trade receivables		109,397		119,096	-		-
Prepayments		1,550,252		851,872	68,258		22,410
		1,659,649		970,968	68,258		22,410
Analysis of trade receivab	les based on	age of invoices					
	< 30						
	\$'000						
		31 - 60	61 -90	> 90	Total Gross	ECL	Total Net
		\$'000	\$'000	\$'000	\$'000	\$'000	\$'000
2022	65,558	-	-	43,839	109,397	-	109,397
2021	73,500	-	45,097	499	119,096	-	119,096

The Group applies the IFRS 9 simplified approach to measuring expected credit losses (ECL) which uses a lifetime expected loss allowance for all trade receivables. The ECL balance has been determined based on historical data available to management in addition to forward looking information utilising management knowledge. The Company applies a similar approach to measuring ECL for the amounts due from group undertakings.

Trade receivables are amounts due from customers for goods sold or services performed in the ordinary course of business. They are generally due for settlement within 30 days and therefore are all classified as current. The majority of trade and other receivables are non-interest bearing. Where the effect is material, trade and other receivables are discounted using discount rates which reflect the relevant costs of financing. The carrying amount of trade and other receivables approximates fair value.

# 15. Inventory

	Group		
	2022	2021	
	US\$	US\$	
Finished Goods and Component parts	1,711,419	1,426,810	

During the year ended 31 December 2022, a total of US\$597,736 of inventories was included in the statement of comprehensive income as an expense (2021: US\$624,507).

<b>16.</b> Cash and cash equivalents				
	Group		Comp	any
	2022	2021	2022	2021
	US\$	US\$	US\$	US\$
Cash at bank and in hand	16,454,241	28,874,908	1,716,189	2,454,491
17. Share capital				
The issued share capital of the Con	npany was as follow	s:		
Allotted and called up - Ordinary	2022	2022	2021	2021
shares of 0.037p each	No.	US\$	No.	US\$
At beginning of period	209,249,966	101,642	163,212,935	78,200
Issue of shares upon warrant				
exercise	-	-	928,089	474
Issue of shares to investors	-	_	44,932,142	22,881
Issue of shares upon option			. ,	•
exercise	3,797,543	1,821	176,800	87
At end of year	213,047,509	103,463	209,249,966	101,642

On 24 February 2021, the Company issued 61,563 new ordinary shares upon the exercise of share warrants with an exercise price of £0.15 each.

On 25 March 2021, the Company issued 358,713 new ordinary shares upon the exercise of share warrants with an exercise price of  $\pm 0.00037$  each.

On 31 March 2021, 7 April 2021 and 8 April 2021 the Company issued a total of 44,932,142 new ordinary shares of £0.00037 each in the capital of the Company at the issue price of 60 pence per share in a Placing, Subscription and Open Offer for total proceeds of £27 million (before expenses).

On 16 April 2021, the Company issued 467,733 new ordinary shares upon the exercise of share warrants with an exercise price of £0.00037 each.

On 17 May 2021, the Company issued 40,080 new ordinary shares upon the exercise of share warrants with an exercise price of  $\pm 0.00037$  each.

On 23 November 2021, the Company issued 66,800 new ordinary shares upon the exercise of share options with an exercise price of  $\pm 0.025358$  each.

On 9 December 2021, the Company issued 110,000 new ordinary shares upon the exercise of share options with an exercise price of  $\pm 0.15$  each.

On 11 January 2022, the Company issued a total of 133,600 new ordinary shares upon the exercise of share options with an exercise price of £0.02478 each.

On 11 January 2022, the Company issued a total of 132,630 new ordinary shares upon the exercise of share options with an exercise price of £0.15 each.

On 01 February 2022, the Company issued a total of 109,356 new ordinary shares upon the exercise of share options with an exercise price of £0.15 each.

On 05 April 2022, the Company issued a total of 2,057,440 new ordinary shares upon the exercise of share options with an exercise price of £0.00313 each.

On 05 April 2022, the Company issued a total of 93,520 new ordinary shares upon the exercise of share options with an exercise price of £0.02571 each.

On 06 April 2022, the Company issued a total of 267,200 new ordinary shares upon the exercise of share options with an exercise price of £0.00314 each.

On 20 April 2022, the Company issued a total of 260,169 new ordinary shares upon the exercise of share options with an exercise price of £0.15 each.

On 20 April 2022, the Company issued a total of 136,109 new ordinary shares upon the exercise of share options with an exercise price of £0.23 each.

On 22 July 2022, the Company issued a total of 534,400 new ordinary shares upon the exercise of share options with an exercise price of £0.15 each.

On 27 July 2022, the Company issued a total of 73,119 new ordinary shares upon the exercise of share options with an exercise price of £0.15 each.

# 18. Reserves

## Share premium

Share premium represents the excess of subscription amounts for the issue of shares over nominal value of shares issued, less any attributable share issue costs.

## Group re-organisation reserve

The group re-organisation reserve arose on the transaction under which the Group acquired the Subsidiary by way of a group re-organisation.

## Share based payment reserve

Cumulative fair value of options charged to the consolidated income statement net of transfers to the profit or loss reserve on exercised.

## Accumulated losses

Includes all current and prior year retained profits and losses.

## Merger reserve

The balance on the merger reserve represents the fair value of the consideration given in excess of the nominal value of the ordinary shares issued in an acquisition made by the issue of shares where the transaction qualifies for merger relief under the Companies Act 2006.

# 19. Share-based payments

## Share options

The Company grants share options at its discretion to Directors, management and employees. These are accounted for as equity settled transactions. Should the options remain unexercised after a period of ten years from the date of grant the options will expire unless an extension is agreed to by the board. Options are exercisable at a price equal to the Company's quoted market price on the date of grant or an exercise price to be determined by the board.

Details of share options granted, exercised, lapsed and outstanding at the year-end are as follows:

	Number of share options 2022	Weighted average exercise price (US\$) 2022	Number of share options 2021	Weighted average exercise price (US\$) 2021
Outstanding at beginning of year	24,443,312	0.50	16,884,322	0.19
Granted during the year	1,941,000	0.71	8,580,000	1.11
Exercised during the year	(3,797,543)	0.07	(176,800)	0.14
Forfeited/lapsed during the year	(3,202,198)	0.99	(844,210)	1.01
Outstanding at end of the year	19,384,571	0.51	24,443,312	0.50
Exercisable at end of the year	13,751,273	0.34	13,055,517	0.14

Date Granted	No. of options	Exercise price	Vesting conditions
08 March 2022	70,000	52 pence	Time-based <sup>1</sup>
13 April 2022	500,000	55 pence	Time-based <sup>1</sup>
04 May 2022	500,000	52 pence	Time-based <sup>1</sup>
23 June 2022	246,000	48 pence	Time-based <sup>1</sup>
25 August 2022	573,000	61 pence	Time-based <sup>1</sup>
20 October 2022	52,000	49 pence	Time-based <sup>1</sup>
	1,941,000	-	

 $<sup>^1</sup>$  25% of the options shall vest on the one-year anniversary of the employee's date of hire with the remaining 75% vesting in equal portions over the 36 months following the one-year anniversary of the employee's date of hire.

The options outstanding as at 31 December 2022 have an exercise price in the range of US\$0.0041 to US\$1.19 (2021: US\$0.0041 to US\$1.19).

The fair value of options granted during the year has been calculated using the Black Scholes model which has given rise to fair values per share of between US\$0.23 and US\$0.47. This is based on risk-free rates of between 1.8% and 3.9%, volatility of between 58% and 80% and expected life of 4 years.

The Black Scholes calculations for the options resulted in a charge of US\$1,205,247 (2021: US\$1,814,882) which has been expensed in the year. The weighted average remaining contractual life of the share options is 6.37 years (2021: 6.85 years). The weighted average share price at the date of exercise for all share options exercised during the period was US\$0.75 (2021: \$0.58). All share options are equity settled on exercise.

#### Share warrants

The Company grants share warrants at its discretion to Directors, management, employees, advisors and lenders. These are accounted for as equity settled transactions. Terms of warrants vary from agreement to agreement.

Details for the warrants granted, exercised, lapsed and outstanding at the year-end are as follows:

	Number of share options 2022	Weighted average exercise price (US\$) 2022	Number of share options 2021	Weighted average exercise price (US\$) 2021
Outstanding at beginning of year	3,054,129	0.01	3,994,165	0.09
Exercised during the year	-	-	(928,089)	0.34
Forfeited/lapsed during the year	-	-	(11,947)	0.34
Outstanding at end of the year	3,054,129	0.01	3,054,129	0.01
Exercisable at end of the year	3,054,129	0.01	3.054,129	0.01

The weighted average remaining contractual life of the share warrants is 1.55 years (2021: 2.55 years). The weighted average share price at the date of exercise for all share warrants exercised during the period was US\$nil (2021: US\$0.68).

# 20. Provision for contingent consideration

	Group		Company	
	2022 US\$	2021 US\$	2022	2021 US\$
Provision for contingent	316,000	316,000	US\$ -	<i>U</i> 3\$ -
consideration	323,000	310,000		

On 19 December 2011, the Subsidiary entered into an agreement with a third party to purchase various assets, including patents, trademarks, a license agreement and physical inventory. As consideration for this transaction, the Subsidiary agreed to pay 5 per cent. of gross revenue on clinical sales of products that are sold related to the patents purchased, for seven years from the date of the commercial sale. As of 31 December 2022, the fair value of this contingent consideration was US\$316,000 (2021: US\$316,000). This liability is valued based on a probability weighted expected return method using projected future cash flows. There were no significant events in the year ended 31 December 2022 necessitating revision of the probability weighted expected value of the contingent consideration.

There was therefore US\$Nil profit or loss arising on revaluation of contingent consideration during the year ended 31 December 2022 (2021: US\$Nil).

	Group		Сотра	ny
	2022	2021	2022	2021
	US\$	US\$	US\$	US\$
Arising from service contracts				
Balance brought forward	254,741	260,717	-	-
Additions	69,809	77,603		
Revenue taken in year	(106,121)	(83,579)	-	-
Balance carried forward	218,429	254,741		-
Current	89,725	108,994	-	-
Non-current	128,704	145,747	-	-
	218,429	254,741		-
22. Trade and other payables				
	Gro	ир	Compai	ny
Amounts falling due within one	2022	2021	2022	2021

	Gro	oup	Cor	mpany
Amounts falling due within one	2022	2021	2022	2021
year	US\$	US\$	US\$	US\$
Trade payables	597,363	405,953	45,861	40,887
Accruals and other payables	1,381,638	1,325,161	114,767	65,129
	1,979,001	1,731,114	160,628	106,016
	Gro	oup	Coi	mpany
Amounts falling due after one	2022	2021	2022	2021
year	US\$	US\$	US\$	US\$
Accruals and other payables	360,000			

Trade payables principally comprise amounts outstanding for trade purchases and ongoing costs and are payable within 1 year.

The Directors consider the carrying value of all financial liabilities to be equivalent to their fair value.

# 23. Changes in liabilities from financing activities

## Group

Lease liability	1 January 2021 US\$ 221,428	Cash flows US\$ (143,170)	Non-cash changes US\$ 411,528	31 December 2021 US\$ 489,786
Total liabilities from financing activities	221,428	(143,170)	411,528	489,786
	1 January 2022 US\$	Cash flows US\$	Non-cash changes US\$	31 December 2022 US\$
Lease liability	489,786	(154,710)	23,761	358,837
Total liabilities from financing activities	489,786	(154,710)	23,761	358,837

# 24. Leases

# Nature of leasing activities

The group leases properties in the jurisdiction in which it operates with all lease payments fixed over the lease term.

	2022	2021
	No.	No.
Number of active leases	2	2

The Group discounts the lease payments using its incremental borrowing rate at the commencement date of the lease. The weighted-average rate applied is 10%.

# Right-of-use assets

	Land and
	Buildings
	US\$
At 1 January 2021	184,213
Additions	378,767
Amortisation expense	(140,164)
At 31 December 2021	422,816
At 1 January 2022	422,816
Amortisation expense	(148,528)
At 31 December 2022	274,288

		Land and
		Buildings
		US\$
At 1 January 2021	•	221,428
Additions		390,427
Interest expense		21,101
Lease payments		(143,170)
At 31 December 2021		489,786
At 1 January 2022		489,786
Interest expense		23,761
Lease payments		(154,710)
At 31 December 2022		358,837
Analysis of lease liabilities		
Maturity of the lease liabilities is analysed as follows:		
	2022	2021
	US\$	US\$
Within 1 year	142,146	130,949
Later than 1 year and less than 5 years	216,691	358,837
	358.837	489.786

#### 25. Commitments

#### Royalty commitments

The Subsidiary has entered into three agreements requiring royalty payments. One agreement is conditional and requires a payment of 5 per cent. of gross revenue on clinical sales during the payment period beginning on the date a product is first commercially sold, contingent on receiving FDA approval, and ending seven years from that date. A separate agreement requires payments of 0.25 per cent of net sales of machines, and 20 per cent of any sublicensing income for a specific method of use of patent beginning in 2016. Additionally, beginning five years after the effective date of 1 February 2021, there are minimum yearly royalties of US\$5,000. The third agreement requires a fixed payment of US\$250,000 for use of patents.

#### 26. Financial instruments

The Group has exposure to the following key risks related to financial instruments:

- I. Market risk
- II. Credit risk
- III. Liquidity risk

This note presents information about the Group's exposure to each of the above risks, the Group's objectives, policies and processes for measuring and managing risk, and the Group's management of capital. Further quantitative disclosures are included throughout these consolidated Financial Statements.

The Group uses financial instruments including cash, loans, as well as trade receivables and payables that arise directly from operations.

Due to the simple nature of these financial instruments, there is no material difference between book and fair values, discounting would not give a material difference to the results of the Group and the Directors believe that there are no material sensitivities that require additional disclosure.

# (a) Credit risk

Credit risk refers to the risk that a counterparty will default on its contractual obligations resulting in financial loss to the Subsidiary. In order to minimise the risk, the Subsidiary endeavours only to deal with companies which are demonstrably creditworthy and this, together with the aggregate financial exposure, is continuously monitored. The maximum exposure to credit risk is the value of the outstanding amount. The Group considers the banks and financial institutions have low credit risks. Therefore, the Group is of the view that the loss allowance is immaterial and hence no provision is required.

The Directors do not consider that there is any concentration of risk within either trade or other receivables. There are no impairments to trade or other receivables in each of the years presented.

# Categories of financial instruments

	G	roup	Com	pany
Financial assets at measured at	2022	2021	2022	2021
amortised cost	US\$	US\$	US\$	US\$
Cash and cash equivalents	16,454,241	28,874,908	1,716,189	2,454,491
Trade and other receivables - current	109,397	119,096	-	-
Other receivables - non-current	5,539	5,539	-	-
Financial liabilities at measured at amortised cost				
Trade and other payables- current	360,000	-	-	-
Other payables - non-current	1,979,001	1,731,114	160,629	106,016

## Capital risk management

The Group manages its capital to ensure that it will be able to continue as a going concern while maximising returns to shareholders through the optimisation of capital structure. The Group is funded by equity. Equity comprises share capital, share premium, share-based payment reserves, group re-org reserves and accumulated

losses and is presented in the statement of financial position. In order to maintain or adjust the capital structure, the Group may adjust the amount of dividends paid to shareholders, return capital to shareholders or issue new shares

The Group manages the capital structure and makes adjustments to it in the light of changes to economic conditions and risks.

#### (b) Market risk

There is no interest risk exposure to the group or the company. The Company made unsecured interest-free loans to its subsidiary and are expected to be repaid in the future as the subsidiary is revenue generative.

## (C) Liquidity risk

A maturity analysis of the Group's financial liabilities is shown below:

2022	Carrying amounts	Undiscounted cash flow	Less than a year	1-2 years	2-5 years
Trade and other					
payables	2,339,001	2,339,001	1,979,001	240,000	120,000
Lease liabilities	358,837	384,435	158,135	150,248	76,052
	2,697,838	2,723,436	2,137,136	510,248	76,052
2021					
Trade and other					
payables	1,731,114	1,731,114	1,731,114	-	-
Lease liabilities	489,786	539,145	154,710	158,135	226,300
	2,220,900	2,270,259	1,885,824	158,135	226,300

#### Capital risk management

As highlighted earlier in these financial statements, the presentation currency of the Group is the US dollar. The Group has foreign currency denominated assets and liabilities. Exposure to exchange rate fluctuations therefore arises. The Group pays for invoices denominated in a foreign currency in the same currency as the invoice and therefore suffers from a level of foreign currency risk, but this is immaterial. The Group did not enter into any derivative financial instruments to manage its exposure to foreign currency risk in the year.

The carrying amount of the Group's foreign currency denominated monetary assets and liabilities at 31 December 2022 is as follows:

	2022	2021
	USD \$	USD \$
British pound sterling		
Cash balances	1,716,189	2,454,491
	1,716,189	2,454,491

At 31 December 2022, if all foreign currencies in which the Group transacts had strengthened or weakened by 10% against the US dollar with all other variables held constant, post-tax loss for the would have been increased/(decreased) by:

	2022	2021
	US\$	US\$
Strengthened by 10% - increase in post-tax loss	171,619	245,449
Weakened by 10% - decrease in post-tax loss	(171,619)	(245,449)

The rate of 10% is the sensitivity rate used when reporting foreign currency risk internally to key management personnel and represents management's assessment of the reasonable possible change in foreign exchange rates. The sensitivity analysis includes only outstanding foreign currency denominated monetary items and adjusts their translation at year-end for a 10% change in foreign currency rates. A positive number above indicates an increase in loss (increase in profit) or other equity where the US\$ strengthens by 10% against the relevant currency. For a 10% weakening of the US\$ against the relevant currency, there would be an equal and opposite impact on the profit or loss and other equity.

## 27. Contingent liabilities

The Directors are not aware of any material contingent liabilities, except for the contingent consideration detailed in note 20.

## 28. Related party transactions

Remuneration of the key management personnel has been disclosed in Note 5.

## 29. Events after the reporting period

Between 1 January 2023 and 20 April 2023, the Company granted options over a total of 325,000 ordinary shares of £0.00037 each in the capital of the Company to three new employees. The options vest over a four-year period and have an exercise price equal to the closing price on the date of grant.

On 17 April 2023, the Company announced the appointment of Daniel Brague, a Non-Executive Director of the Company, as a consultant to the Company to provide strategic advice to the Company's commercial team. Under the terms of the consultancy contract, the Company will pay Mr. Brague an hourly fee of \$300. The fee is capped at \$100.000 in total.

#### Notice of the Annual General Meeting

#### POLAREAN IMAGING PLC

(Incorporated in England and Wales under the Companies Act 2006 with company number 10442853)

#### NOTICE OF ANNUAL GENERAL MEETING

#### THIS DOCUMENT IS IMPORTANT AND REQUIRES YOUR IMMEDIATE ATTENTION

If you are in any doubt as to what action you should take, you are recommended to seek your own financial advice from your stockbroker or other independent adviser authorised under the Financial Services and Markets Act 2000.

If you have recently sold or transferred all of your shares in Polarean Imaging plc, please forward this document, together with the accompanying documents, as soon as possible either to the purchaser or transferee or to the person who arranged the sale or transfer so they can pass these documents to the person who now holds the shares.

It is intended that the Annual General Meeting (the "AGM") of Polarean Imaging plc (the "Company") will be held at the Company's office at 2500 Meridian Parkway, Suite 175, Durham, NC 27713 USA at 2:00 p.m. BST (9:00 a.m. EST) on 28 June 2023. The Company understand and recognises the importance of the AGM and the Board greatly values the opportunity to meet shareholders in person. However, we understand that this may not be possible or desirable for all whom wish to attend, therefore, the Company will offer shareholders the option to participate in the AGM remotely via a Zoom conference call. If you wish to use this facility, please Company' investors relations firm, Walbrook Public Relations, by emailing polarean@walbrookpr.com who will provide further information. However, shareholders will not be able to vote at the meeting when joining via the Zoom conference call. Shareholders are therefore asked, whether or not they propose to attend the AGM, to exercise their votes and appoint the Chairman of the AGM as their proxy by completing the form of proxy sent to them with this document and return it to the Company's registrars as soon as possible. They must receive it by 2:00 p.m. BST (9:00 a.m. EST) on 26 June 2023 (or, in circumstances where the AGM is adjourned to a date later than 48 hours after the time specified for the Meeting, 48 hours before the time of the adjourned meeting, excluding any UK non-working days).

NOTICE IS HEREBY GIVEN that the Annual General Meeting of Polarean Imaging plc (the "Company") will be held at the Company's office at 2500 Meridian Parkway, Suite 175, Durham, NC 27713 USA at 2:00 p.m. BST (9:00 a.m. EST) on 28 June 2023 for the purpose of considering and, if thought fit, transacting the following business:

## ORDINARY BUSINESS

To consider and, if thought fit, pass the following resolutions which will be proposed as ordinary resolutions:

- To receive and consider the Company's audited accounts for the year ended 31 December 2022 and the Directors' of the Company (the "Director(s)") and auditors' reports thereon.
- To consider and approve the remuneration report as detailed in the Company's annual report and accounts.
- To re-appoint Crowe UK LLP as auditor of the Company (the "Auditor") to hold office until the conclusion of the next general meeting at which accounts are laid and to authorise the Directors to
- fix the Auditor's remuneration.

  To re-elect Marcella Ruddy as a Director, who retires in accordance with article 78 of the Articles, and who, being eligible, offers herself for re-election.
- 5. To re-elect Juergen Laucht as a Director, who retires in accordance with article 78 of the Articles, and who, being eligible, offers himself for re-election.
- who, being eligible, offers himself for re-election.
  To re-elect Cyrille Petit as a Director, who retires in accordance with article 83 of the Articles, and who, being eligible, offers himself for re-election.
  To approve the amendments to the rules of the Polarean Imaging plc Share Option Plan (the "Plan") as further described on page 19 of the Annual Report and to authorise the Directors to do all such other acts and things they may consider appropriate to implement the amended plan.

  To generally and unconditionally authorise the Directors for the purpose of section 551 of the
- Companies Act 2006 (the "Act"), in substitution for all existing authorities to the extent unused, to exercise all the powers of the Company to allot or grant rights to subscribe for or to convert any security into shares in the Company:

a) up to 10,000,000 ordinary shares of £0.00037 each ("Ordinary Shares") in respect of the Plan; and b) otherwise than pursuant to paragraph (a) above, up to 31,957,126 Ordinary Shares (being 15 per cent. of the total number of Ordinary Shares in issue as at the date of this notice),

provided that this authority shall expire on the earlier of 15 months after the date of passing of this resolution or the conclusion of the annual general meeting of the Company next following the passing of this resolution, save that the Company may, before such expiry, make an offer or agreement which would or might require shares or equity securities, as the case may be, to be allotted or such rights granted after such expiry and the Directors may allot shares or equity securities or grant such rights, as the case may be, in pursuance of such offer or agreement notwithstanding that the authority conferred by this resolution has expired.

## **SPECIAL BUSINESS**

To consider and, if thought fit, pass the following resolution as a special resolution:

9 . Subject to the passing of resolution 8 above, to empower the Directors, pursuant to the general authority conferred on them and section 570 of the Act, to allot equity securities (within the meaning

of section 560 of the Act) for cash as if section 561 of the Act did not apply to any such allotment, provided that this power shall be limited to the allotment of equity securities:

a) made in connection with an offer of securities, open for acceptance for a fixed period, to holders of Ordinary Shares of the Company on the register on a fixed record date in proportion (as nearly as may be) to their then holdings of such Ordinary Shares (but subject to such exclusions or other arrangements as the Directors may deem necessary or expedient to deal with any legal or practical problems under the laws or requirements of any recognised regulatory body or any stock exchange in any overseas territory or in connection with fractional entitlements); and/or

b) wholly for cash (otherwise than pursuant to paragraph 9(a) above) up to an aggregate number of 31,957,126 Ordinary Shares.

This authority shall expire on the earlier of 15 months after the date of passing of this resolution and the conclusion of the annual general meeting of the Company next following the passing of this resolution but the Company may, before such expiry, make an offer or agreement which would or might require shares or equity securities, as the case may be, to be allotted or such rights granted after such expiry and the Directors may allot shares or equity securities or grant such rights, as the case may be, in pursuance of such an offer or agreement notwithstanding that the power conferred by this resolution has expired.

By Order of the Board

Stephen Austin Company Secretary 25 May 2023 Registered Office: 27-28 Eastcastle Street London W1Q 8DH

#### **NOTES**

A shareholder entitled to attend and vote at the meeting convened by this notice is entitled to appoint one or more proxies to exercise all or any of their rights to attend, speak and vote on their behalf at the AGM. A proxy need not be a shareholder.

# (1) Arrangements for the meeting

Shareholders who wish to attend the AGM in person should arrive at the venue in good time to allow their attendance to be registered. Shareholders who wish to participate in the meeting remotely via the Zoom conference call should contact the Company's investor relations firm, Walbrook Public Relations, by emailing polarean@walbrookpr.com who will provide further information. However, Shareholders will not be able to vote at the meeting when joining via the Zoom conference call. The Board:

- encourages Shareholders to submit their votes by proxy as early as possible, and Shareholders
  are encouraged to appoint the Chairman of the meeting as their proxy. All proxy appointments
  should be received by no later than 2:00 p.m. BST on 26 June 2023;
- strongly recommends CREST members to vote electronically through the CREST electronic proxy
  appointment service as your vote will automatically be counted. In addition, the Company has
  also decided that proxy appointments can also be submitted by Shareholders electronically
  (even outside CREST) by logging on to www.shareregistrars.uk.com, clicking on the "Proxy Vote"
  button and then following the on-screen instructions (you can locate your log-in details on the
  top of the proxy form). Please contact Share Registrars Limited contact number on +44 (0) 1252
  821390 for any further guidance. Dealing with paper proxies requires physical interaction
  such as post sorting and delivery, evaluation and manual input.
- proposes that voting at the meeting will be conducted by means of a poll on all resolutions, with each Shareholder having one vote for each share held, thereby allowing all those proxy votes submitted and received prior to the meeting to be counted; and
- encourages you to submit any question that you would like to be answered at the meeting by sending it, together with your name as shown on the Company's register of members and the number of shares held, to the following email address: polarean@walbrookpr.com so that it is received by no later than 2:00 p.m. BST on 26 June 2023. Please insert "AGM Shareholder Questions" in the subject header box of your email. The Company will endeavour to respond to all questions received from Shareholders at the AGM or within seven days following the AGM.
- (2) To appoint a proxy, shareholders should use the form of proxy enclosed with this notice of AGM. Please carefully read the instructions on how to complete the form of proxy. For a proxy to be effective,

the instrument appointing a proxy together with the power of attorney or such other authority (if any) under which it is signed or a notarised certified copy of the same must be deposited with the Company's registrars, Share Registrars Limited of 3 The Millennium Centre, Crosby Way, Farnham, Surrey, GU9 7XX, United Kingdom (the "Registrars") or shareholders can submit their vote(s) by logging on to www.shareregistrars.uk.com, clicking on the "Proxy Vote" button and then following the on-screen instructions (you can locate your log-in details on the top of the proxy form) by 2:00 p.m. BST on 26 June 2023, or, if the AGM is adjourned, 48 hours before the time fixed for the adjourned meeting (excluding any part of a day that is not a business day). The completion and return of a form of proxy does not preclude a shareholder from subsequently attending and voting at the AGM in person if he or she so wishes. If a shareholder has appointed a proxy and attends the AGM in person, such proxy appointment will automatically be terminated.

- (3) Pursuant to Regulation 41 of Uncertificated Securities Regulations 2001, the Company specifies that only those shareholders on the register of members at 2:00 p.m. BST on 26 June 2023 or, if the meeting is adjourned, 48 hours before the time of the adjourned meeting (excluding any part of a day that is not a business day), shall be entitled to attend or vote at the AGM in respect of the number of ordinary shares of £0.00037 each (the "Ordinary Shared") registered in their name at that time. Changes to the register of members after that time shall be disregarded in determining the rights of any person to attend or vote at the AGM.
- (4) Any Shareholder may insert the full name of a proxy or the full names of two alternative proxies of the Shareholder's choice in the space provided with or without deleting 'the Chairman of the meeting.' A proxy need not be a Shareholder but must attend the meeting to represent the relevant Shareholder. The person whose name appears first on the Form of Proxy and has not been deleted will be entitled to act as proxy to the exclusion of those whose names follow. If this proxy form is signed and returned with no name inserted in the space provided for that purpose, the Chairman of the meeting will be deemed to be the appointed proxy. Where a Shareholder appoints as his/her proxy someone other than the Chairman, the relevant Shareholder is responsible for ensuring that the proxy attends the meeting and is aware of the Shareholder's voting intentions. Any alteration, deletion or correction made in the Form of Proxy must be initialled by the signatory/ies.
- (5) A shareholder may appoint more than one proxy provided that each proxy is appointed to exercise the rights attached to a different Ordinary Share or Ordinary Shares held by that shareholder. A shareholder may not appoint more than one proxy to exercise rights attached to any one Ordinary Share. If a shareholder wishes to appoint more than one proxy, they should contact the Registrars on 01252 821390, +44 1252 821390 from overseas. Lines are open from 9.00 a.m. to 5.00 p.m. Monday to Friday, excluding public holidays. Alternatively, you may write to the Registrars at Share Registrars Limited, 3 The Millennium Centre, Crosby Way, Farnham, Surrey, GU9 7XX, United Kingdom for additional proxy forms and for assistance.
- (6) Any corporation which is a shareholder can appoint one or more corporate representatives who may exercise on its behalf all of its powers as a shareholder provided that they do not do so in relation to the same Ordinary Share.
- (7) As at the close of business on the date immediately preceding this notice, the Company's issued share capital comprised 213,047,509 Ordinary Shares. Each Ordinary Share carries the right to vote at the AGM and, therefore, the total number of voting rights in the Company as at close of business on the date immediately preceding this notice is 213,047,509.
- (8) A shareholder's instructions to the proxy must be indicated in the appropriate space provided. To abstain from voting on a resolution, select the relevant 'Vote withheld' box. A vote withheld is not a vote in law, which means that the vote will not be counted in the calculation of votes for or against the resolution. If no voting indication is given, your proxy will vote or abstain from voting at his or her discretion. Your proxy will vote (or abstain from voting) as he or she thinks fit in relation to any other matter which is put before the meeting.
- (9) This form of proxy must be signed by the appointor, or his attorney duly authorised in writing. The power of attorney or other authority (if any) under which the form of proxy is signed, or a notarised certified copy of the power or authority, must be received by the Registrars with the form of proxy. If the appointor is a corporation, the form of proxy should be signed on its behalf by an attorney or duly authorised officer or executed as a deed or executed under common seal. In the case of joint holders, the signature of any one of them will suffice, but the names of all joint holders should be stated.
- ( 1 0 ) CREST members who wish to appoint a proxy or proxies through the CREST Electronic Proxy Appointment Service may do so for the AGM to be held at 2:00 p.m. BST on 28 June 2023 and any adjournment(s) thereof by following the procedures described in the CREST manual. All messages relating to the appointment of a proxy or an instruction to a previously appointed proxy, which are to be transmitted through CREST, must be received by the Registrars (ID 7RA36) no later than 2:00 p.m. BST on 26 June 2023, or, if the AGM is adjourned, 48 hours before the time fixed for the adjourned meeting (excluding any part of a day that is not a business day).
- (11) In order to revoke a proxy instruction, you will need to inform the Company by sending a signed hard copy notice clearly stating your intention to revoke your proxy appointment to the Registrars. In the case of a shareholder which is a company, the revocation notice must be executed in accordance with note 12 below. Any power of attorney or any other authority under which the revocation notice is signed (or a duly certified copy of such power or authority) must be included with the revocation notice and must be received by the Registrars not less than 48 hours (excluding any part of a day that is not a business day) before the time fixed for the holding of the AGM or any adjourned meeting (or in the case of a poll before the time appointed for taking the poll) at which the proxy is to attend, speak and to vote.

If you attempt to revoke your proxy appointment but the revocation is received after the time specified then, subject to the paragraph directly below, your proxy appointment will remain valid.

(12) A corporation's form of proxy must be executed under either its common seal, if any, or under the hand of a duly authorised officer or attorney, in each case as required under the laws of its relevant jurisdiction.



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