

Polarean Imaging Plc Group Annual Report & Accounts 2018

Company Number 10442853

# **Group Annual Report and Financial Statements**

for the year ended 31 December 2018

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# **Company Information**

### **Directors & Advisers**

DirectorsRichard MorganNon-Executive ChairmanRichard HullihenChief Executive Officer

Richard Hullihen Kenneth West Bastiaan Driehuys, PH.D.

Bastiaan Driehuys, PH.D. Chief Technology Officer
Robert ("Bob") Bertoldi Non-Executive Director
Jonathan Allis Non-Executive Director
Juergen Laucht Non-Executive Director

**Chief Operating Officer** 

Company Secretary Stephen Austin

Chief Financial Officer Charles Osborne

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Company Number Registered in England and Wales Number 10442853

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# **Chairman's Statement**

The most immediate challenge facing the Company upon completion of the IPO in March 2018 was the start of the clinical trials. Satisfactory completion of the clinical trials is a necessary condition for successful commercial development as we go forward, although it is far from being the only key to our success.

The trials are now nearing completion. No clinical trial is ever straight forward and the team has worked closely with the several advisors that have guided the design, launch and prosecution of the trials, to ensure that they are proceeding to plan. As we announced on 11 June 2019, we have elected to bring online a third trial site and we are grateful to our valued collaborators at the University of Cincinnati for their help with the initiation of this site, which we believe should ensure the timely completion of enrolment in both trials by the end of the third quarter of 2019. That should allow us to file our New Drug Application ("NDA") with the FDA and, assuming approval, is expected to enable us to make our first commercial unit sales by the end of 2020.

While the clinical trials we are conducting are a critical part of the business plan, they are not the only part. The Company has continued to meet expectations in relation to sales of additional pre-clinical units to existing and new institutional customers. This has brought the total number of systems in use or on order to 24 and the majority of those are with leading medical institutions who are conducting research and additional clinical trials into the use of hyperpolarized 129 Xenon using MRI (129Xe MRI). At present there are at least 42 clinical trials into the use of 129Xe MRI showing on the FDA website. We were particularly pleased to be able to announce on 21 May 2019 receipt of the third year of grant from the NIH / SBIR which is funding the work being done jointly with Cincinnati Children's Hospital into the use of 129Xe MRI in paediatric populations. Alongside the work being done by SickKids in Canada, and others, into pediatric populations we believe we can look forward to 129Xe MRI making a materially positive medical contribution to the diagnosis and monitoring of treatment of pulmonary health conditions in children, including those suffering from cystic fibrosis.

During the year a number of key advances were made in applications of the technology to gas exchange and beyond. Many of the medical issues that arise in patients with compromised pulmonary function occur as a result of deficiencies in the body's ability to absorb oxygen out of air and into the bloodstream. Some of these medical issues, like Idiopathic Pulmonary Fibrosis ("IPF"), cannot readily be diagnosed accurately using existing techniques but they are serious conditions that are increasingly being targeted by the pharmaceutical companies for drug development. Accurate diagnosis and monitoring is one critical aspect of the effective medication of these conditions and we believe <sup>129</sup>Xe MRI can help to address this unmet medical need. In late 2018 we extended our collaboration with Duke University by securing the intellectual property rights to an entirely new application, in pulmonary vascular disease, including pulmonary arterial hypertension ("PAH"). We are already in discussion with several companies that have developed medications for PAH and other conditions (COPD and asthma for example) in the expectation that <sup>129</sup>Xe MRI can make a significant difference in both the development of new drugs and in the management of these conditions in the clinic.

Our first nine months as a public company included the completion of two additional financing rounds, the second of which closed at the end of 2018. The capital market environment for small medical technology companies was challenging throughout the year and the Polarean IPO was one of very few successful public listings in the sector on the AIM market in 2018. We were fortunate to be able to complete those financing rounds, which provided additional support for the clinical trials.

We believe that partnering with pharmaceutical and other companies to facilitate the development and use of their products is a key part of Polarean's future development. We already have relationships with several companies that have expressed an interest in partnering with us. Such relationships can help us expand our development activities in the near term and, following FDA approval, to expand access to and support a presence in deployment of Polarean's technology as we reach into the clinical setting and help expand the treatment options available to patients. We have also consistently stated our intention to access markets outside the United States through partnerships and we are pleased to note a growing interest in partnering opportunities to expand our geographical footprint in that way.

The team has done a great job in efficiently producing and shipping new systems to our customers, while working closely with our installed base to provide service and support to their existing systems. As our installed base grows, this becomes a proportionally larger challenge, in addition to the continuing work in hand to improve the design and performance of our systems and to plan for the future evolution of the product. The manufacture of the equipment was successfully outsourced and the last five machines have been built under the GMP standards which are required both for pivotal clinical trials and the clinical use of this technology.

# **Chairman's Statement**

### Continued

We were delighted to be able to add Chuck Osborne to our team as Chief Financial Officer in April 2019 and welcome his help in addressing the many challenges that lie ahead as we grow the Company.

We hope to be able to announce the completion of our clinical trials in the next few months and look forward to working with the FDA when we seek approval to allow marketing of the technology next year. This will be another major and exciting phase change for the Company which we will report on more fully in the coming months. We continue to look forward with determination and high confidence in the strength of the technology and the commitment of the team.

Richard Morgan Non-Executive Chairman

26 June 2019

# 2018 - Year of Development and Accomplishment

Polarean and its subsidiaries (the 'Group') began their first full year focused on preparation for the Phase III Clinical trials. Having finalised contracts with Contract Research Organisations and with the two university sites for the trials, we planned and executed a Pilot Study which closely matched the trial protocol in order to prove that the structure and specifications of the trials were met in the "non-inferiority" structure of the trial. We conducted that study at one of the two trial sites, using the same equipment and methods of the Phase III trial protocol. That study was successful and gave the Group the confidence to initiate the trials.

## The Opportunity

The US Healthcare system annual burden of pulmonary disease is US\$150 billion and the Directors still see a tremendous opportunity to bring our technology's quantitative, reproducible, non-invasive method for diagnostic and therapeutic guidance to medicine. We have begun to develop the healthcare economic analyses to support the adoption by providers of our technology, working with experts in the field. Over the planning horizon of the first 48 months post commercial launch, the Group intends to address the high end of US academic and teaching hospital market segment, which comprises approximately the top 1,000 institutions nationally. The combined addressable market there for our products approaches US\$500 million.

While working to achieve FDA approval for clinical use, Polarean continues to serve the medical imaging research market by providing xenon polarisers to enable functional MRI of the pulmonary system. This brings dynamic, high-resolution, regional, image-based information to pulmonary physicians and researchers whose best alternative tool is spirometry, a relatively inaccurate measurement of expired breath. Current imaging technologies are not often used for assessing lung function, despite the revolutionary effects of MRI in other medical applications.

### **Our Clinical Trials**

Our Phase III Clinical Trials are head-to-head, non-inferiority trials which are comparing our technology to an existing nuclear medicine technique using radioactive <sup>133</sup>Xe and gamma cameras. The trials involve 80 patients in total and are being conducted at three of our closest collaborative sites, the University of Virginia Duke University ("Duke") and the University of Cincinnati. We are characterising ventilation in two sets of patients being evaluated for surgical procedures: those who are being evaluated for lung lobar resection surgery and those being evaluated for lung transplant. In each case their pre-operative expired vital capacity is measured through spirometry. Our technology and the existing nuclear medicine standard of care are used to assess the remaining post-operative vital capacities. Our trial has focused entirely on the pre-operative assessment and it makes no difference whether the patient is chosen for surgery. We are at an advanced stage in the trial and expect enrolment to conclude in the third quarter of 2019.

### **Our Operations**

The Group completed the transition of manufacturing to a local certified medical device manufacturer. In 2018, we built and shipped five units and one upgrade. This is the largest production volume we have achieved. This included the transition to GMP level production for the Clinical Trial units and all units thereafter. We will continue to improve the production capability of our provider moving forward.

### R&D

We continued to invest in our intellectual property portfolio during the year. Key new patent filings involving gas exchange and pulmonary vascular disease were added, and an expanded and enhanced license agreement with Duke was achieved.

### 2018 Financial Results

Broadly speaking, our operating performance was as we expected in 2018, with revenues slightly higher than expected at US\$2.439 million and expenses slightly lower than expected. In addition, we raised US\$1M (before expenses) in July 2018 in a placing based on investor demand and US\$4 million (before expenses) in December 2018 (a significant majority of the proceeds from the December 2018 placement were received by the Company in early 2019) in a placing designed to fund the company through our Clinical Trial enrolment. During the period, we benefitted from the Year 2 proceeds of the NIH SBIR Grant which we have jointly with the University of Cincinnati Children's Hospital. Our pricing and margins have maintained throughout the year. It is still the case that the majority of our research systems are procured via grant mechanisms and while the outcomes are typically known with some certainty, the ultimate fiscal timing of these projects is difficult to predict with certainty.

### **Chief Executive Officer's Statement**

continued

# 2019 and Beyond

We plan to complete enrolment of our Phase III trials in the third quarter of 2019 and look forward to the readout of both indications with confidence, based on the results of our Pilot Study. We will proceed with filing our NDA and continue to cautiously plan to receive regulatory approval in the second half of 2020. In the meantime, we continue to collaborate with researchers in the US and abroad and look to expand our installed base of research systems. The exciting new developments in cardiology and pulmonary vascular disease are expanding and our knowledge base about these conditions is expanding.

We have begun early discussions with potential strategic partners in the pharmaceutical industry and in other geographic markets that could lead to important developments in new applications and uses for our technology, expansion into new territories, and which may bring economic benefits to the Group going forward.

Polarean is fortunate to have an outstanding collection of world-class collaborators and customers in both the US and Europe. Additionally, we support the "129Xe MRI Clinical Trials Consortium" and the crucial work they do in collaborative research, training investigators, providing infrastructure for evaluating new techniques, and multi-institution sharing of magnetic resonance (MR) techniques and image analysis methods. We would like to thank the National Heart Lung and Blood Institute for their continued support of our Small Business Innovation Research Program grant with Cincinnati Children's Hospital Medical Center. In addition, we have developed solid working relationships with MRI systems manufacturers and exclusive relationships with global industrial gas suppliers, all key to our future as we scale the business.

On behalf of the entire staff of Polarean Imaging, I would like to thank you for your investment in and support of the Group and we look forward to continuing to develop and deliver this critical life-saving and life-improving technology to physicians and patients everywhere.

Richard Hullihen
Chief Executive Officer
26 June 2019

### 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 hemodynamics, a novel diagnostic approach. The Group also develops and manufactures the high performance MRI radiofrequency (RF) coils which are a required component for imaging 129Xe in the MRI system. The development of these coils by the Group 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'), developer of medical, life science, and technology businesses, which is itself currently quoted on AIM.

### 2. 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 all 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 a number of key milestones are expected to be achieved by the Group in the short to medium term. The most important near-term milestone will be the successful completion of the FDA Phase III clinical trial in the US for the Group's technology. The ongoing 80 patient non-inferiority trial is being conducted at Duke University Medical Center, the University of Virginia and The University of Cincinnati three leading US research hospitals. The trial has enrolled a significant majority of the 80 patients and is expected to complete enrolment by the end of the third quarter of 2019. The Group will file a New Drug Application (NDA) after completion of the current Phase III trial. Upon completion of the Phase III trial and filing of the NDA, the Directors anticipate receiving a broad indication for use from the FDA following the FDA's review period.

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.

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# 3. 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 listed it shares on the AIM Market of the London Stock Exchange

## 4. Information on Polarean, m2m and Strategy of Group

### 4.1 Polarean, Inc. - Background

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 (<sup>3</sup>He), and 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 <sup>129</sup>Xe as a more effective substitute for <sup>3</sup>He in visualising ventilation. GE also began to explore ways in which <sup>129</sup>Xe 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 INDs with the FDA for both <sup>3</sup>He and <sup>129</sup>Xe. By 2010, after an investment of around 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 believe that a clearer path towards regulatory approval now exists. As such, following Admission the Group intends to focus on conducting the clinical studies required for FDA approval to market.

Between 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.

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### 4.3 The Group's Technology and Products

The Subsidiary is a clinical-stage company and its 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**") via 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 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 <sup>129</sup>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, as the physician's ability to clearly identify issues with ventilation and gas exchange on a regional basis, down to the smallest of airways, is enhanced. Hyperpolarisation of the <sup>129</sup>Xe is accomplished by placing a non-radioactive isotope of Xenon (<sup>129</sup>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 <sup>129</sup>Xe whose nuclear magnetic spin is highly aligned but not chemically or biologically different than unpolarised <sup>129</sup>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 and has relationships with GMP gas producers to supply the Group with high purity <sup>129</sup>Xe.

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.

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### 4.5 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 4,000 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 NMR system capable of delivering available electromagnetic field strength, utilised for calibrating absolute polarisation measurements of hyperpolarised gas samples.

# 4.6 The Regulatory Environment

At present, prior to the receipt of any approvals for clinical use, the Group sells 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.

The Group has held regular meetings with the FDA to develop a path towards approval for clinical use and the FDA has indicated its willingness to accept a very broad indication for use for the Group's technology – for the evaluation of pulmonary function – as opposed to its use being limited to any particular pulmonary disease or condition. The FDA has reviewed proposals for the Group's Phase III clinical trials and has provided clearance for the trials to take place. The Phase III trials include a total of 80 patients and the FDA has indicated that it will also accept existing literature-based data in fulfilment of certain safety and toxicology requirements. The Directors believe that this broad indication and limited clinical trial size provides the Group with a sizeable, addressable market at a modest clinical trial cost.

### 4.7 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 currently twelve research institutions worldwide utilising the Group's system and products, including Cincinnati Children's Hospital, the University of Virginia, University of Wisconsin – Madison and Duke University 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. At the date of this report, there are currently 24 Xenon Hyperpolariser units installed at these and several other leading research hospitals and the Group anticipates selling further units for research purposes during the course of the Phase III clinical trial.

### 4.8 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, has been engaged to project manage the trial and will oversee the recruitment of patients for the trial. In addition, Icon Clinical Research Limited will assist with the medical imaging aspects of the trial.

The Group has a long-standing relationship with its strategic investor Nukem Isotopes GmbH, a leading global supplier of <sup>129</sup>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 <sup>129</sup>Xe.

In December 2017 the Group signed a letter of intent ("**Lol**") with Linde Electronics and Speciality Gases, a division of Linde Gas North America LLC ("**Linde**"), in relation to a potential product supply agreement. Under the terms of the Lol, the Group and Linde have agreed to negotiate, prepare and sign a product supply agreement for the supply of industrial gas to the Group, subject to all required licenses and approvals being obtained by the parties. This agreement contains provision for the supply of bulk Xe to be enriched to <sup>129</sup>Xe, and for the blending, packaging, and distribution of its drug product under GMP.

### 4.9 Current Trading and Prospects

Trading of the Group since 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 ahead of the completion of the Phase III clinical trials and the exploitation of the addressable markets for the Group's technology.

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### 4.10 Growth Strategy

The Group estimates that in the short term it will generate additional revenue from the sale of hyperpolarisers to global research institutions and 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. At present, a number of major pharmaceutical companies are working with universities that are well known to the Group, regarding the use of HPX MRI technology to help guide clinical trials of developmental pharmaceutical products which is raising awareness of the Group's technology and product range.

The FDA have accepted the Group's Phase III clinical trial design and upon completion of the Phase III trial and subsequent FDA approval, the Group will adopt 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 1000 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 Group also intends to continue patenting and in-licensing hyperpolarised gas technology IP to protect its current position.

Following completion of the Phase III trial and upon receipt of FDA clearance to market the technology, 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.

Subsequently, the Group will seek to expand 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 using 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 exacerbations;
- · 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 IPF and monitoring of IPF therapy; and
- diagnosis of pulmonary vascular disease (PVD) including pulmonary arterial hypertension (PAH) and monitoring of therapy.

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.

### 5. 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 22 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;

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- 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 jurisdications 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.

### 6. 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 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 Placing and Subscription. 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. 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 United States. See Going Concern discussion above.

#### continued

### 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 have 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 manufacturer and service provider for noble gas <sup>29</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.

### 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.

#### continued

### 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 intends to outsource 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, will be 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 drug-device 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 internal experts that train the outside vendors. The Group has established relationships with two <sup>129</sup>Xe suppliers to mitigate the risk that <sup>129</sup>Xe supply will be a limitation to the development and commercialization of its products.

### Product development timelines

Product development timelines are at risk of delay, particularly since it is not always possible to predict the rate of patient recruitment into clinical trials. 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 utilizes contract research organisations that are experts in recruiting and conducting clinical trials. The Group contracted with an additional clinical site to increase the enrollment rate for the clinical trial.

#### 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. Furthermore, as the Group already has some exposure to the UK market, there is a risk that possible changes resulting from the Brexit negotiations could lead to additional barriers to trade and regulatory divergence which could adversely affect the Group

### Principal mitigation

The Group consults experts for advice in areas such as occupational safety, laboratory practice and human testing. The Group's initial focus is on the US market, so Brexit negotiations should not impact the development pathway for the Group's products. The Group will continue to monitor the Brexit situation and assess the impact on the Group's ability to access capital in the UK.

### 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 has contracted with an expert in the field of reimbursement for healthcare products in the US to determine the best strategy for accessing adequate reimbursement for its products.

**Richard Morgan** 

Non-Executive Chairman

26 June 2019

The Directors present their report on the affairs of Polarean Imaging plc (the "Company") and its subsidiaries, referred to as the Group, together with the audited Financial Statements and Independent Auditors' Report for the year ended 31 December 2018.

### **Principal activities**

The main activity of the Group is a drug device manufacturer and service provider for noble gas polarizer devices, its proprietary <sup>129</sup>Xe drug and ancillary instruments with a special focus on pulmonary imaging.

#### Results and dividends

During the year ended 31 December 2018 the Group recorded a loss after tax of US\$5,454,659 (2017: US\$3,957,821) and a net cash outflow from operating activities of US\$4,676,346 (2017: US\$2,615,901).

The Directors do not recommend the payment of a dividend (2017: US \$nil).

### Going concern

In considering the appropriateness of this basis of preparation, the Directors have reviewed the Group's working capital forecasts for a minimum of 12 months from the date of the approval of this financial information. Based on their consideration the Directors have reasonable expectation that the Group has adequate resources to continue for the foreseeable future and that carrying values of intangible assets are supported. Thus, they continue to adopt the going concern basis of accounting in preparing this financial information.

#### **Future developments**

The Company's future developments are outlined in the Strategic Report on page 11.

### Research design & development

Research and development is performed by employees of the company. The Group is committed to increasing its R&D budget to meet anticipated market demands for additional technology. In addition, the company also inlicenses technology from collaborative academic institutions. Details of R&D carried out during the year are contained in the Strategic Report.

### Financial risk management

Financial risk management policies and objectives for capital management are outlined in the principal risks and uncertainties section of the strategic report on pages 12 to 14 and in note 25 to the financial statements.

### Directors' indemnities

The Group has made qualifying third-party indemnity provisions for the benefit of its Directors, which were made during the year and remain in force at the date of this report.

## Events after the reporting period

Details of significant events since the reporting period are contained in note 28 of the financial statements.

continued

### Directors' emoluments

2018

	Salary, Fees & Bonus	Benefits	Share-Based Payments	Total
	US\$	US\$	US\$	US\$
<b>Executive Directors</b>				_
Bastiaan Driehuys (Note A)	37,500	-	9,780	47,280
Richard Hullihen (Note B)	269,000	-	39,082	308,082
Kenneth West (Note C)	225,000	-	37,098	262,098
Non-Executive Directors				
Richard Morgan (Note A)	86,250	-	9,780	96,030
Jonathan Allis (Note A)	33,750	-	9,780	43,530
Robert Bertoldi (Note A)	41,250	-	9,780	51,030
Juergen Laucht (Note A)	41,250	-	9,780	51,030
Total	734,000	-	125,080	859,080

#### 2017

	Salary, Fees & Bonus	Benefits	Share-Based Payments	Total
	US\$	US\$	US\$	US\$
Executive directors				
Bastiaan Driehuys	-	-	-	-
Richard Hullihen (Note B)	155,714	8,059	-	163,773
Kenneth West (Note C)	121,254	5,727	-	126,981
Non-Executive Directors				
Richard Morgan	-	-	-	-
Jonathan Allis	-	-	-	-
Robert Bertoldi	-	-	-	-
Juergen Laucht	-	-	-	-
Total	276,968	13,786	-	290,754

Note A: The Board agreed to a 100% salary deferral in 2018. These amounts were paid in 2019.

Note B: Richard Hullihen agreed to a salary deferral in 2018 and 2017. The amounts included in salaries are US\$117,437 and US\$51,547, respectively.

Note C: Kenneth West agreed to a salary deferral in 2018 and 2017. The amounts included in salaries are US\$93,750 and US\$46,392, respectively.

## **Directors' interests**

The Directors who held office at 31 December 2018 had the following direct interest in the ordinary shares of the Company at 31 December 2018.

# Directors' beneficial interests in shares of the Company:

	2018 Number	2018 %	2017 Number	2017 %
Richard Morgan	419,018	0.4	-	-
Richard Hullihen	2,137,354	2.1	1,540,211	3.18
Robert Bertoldi	93,333	0.1	-	-
Kenneth West	475,594	0.5	216,085	0.45
Bastiaan Driehuys	12,267,503	12.2	12,007,994	24.77

#### continued

On 16 February 2018 the Company sub-divided its share capital on the basis of 26.71999:1. The number of Ordinary shares in issue in the Company at 31 December 2017 reflects the sub-division.

The shareholdings noted above include those shares held by connected persons of the individual director.

### Directors' beneficial interests in options to subscribe for additional shares of the Company:

	2018 Number	2017 Number
Richard Morgan	534,400	-
Richard Hullihen	2,135,440	-
Robert Bertoldi	534,400	-
Kenneth West	1,913,218	267,200
Bastiaan Driehuys	1,336,000	801,600
Juergen Laucht	534,400	-

On 20 April 2018, the Company issued 10,403,600 Options to certain directors, persons discharging managerial responsibilities ("PDMR") and employees. The exercise price for the Options is £0.15 being the price at which Polarean's Ordinary Shares were placed at Admission. The Options will vest in equal portions on an annual basis on the anniversary of Admission, over a four-year period from the date of Admission. The options term expires on 29 March 2028.

The following directors were a part of the grant of PDMR options were:

- Richard Morgan was granted 534,400 options;
- Richard Hullihen was granted 2,135,440 options;
- Robert Bertoldi was granted 534,400 options;
- Kenneth West was granted 1,646,018 options;
- Bastiaan Driehuys was granted 534,400 options;
- Juergen Laucht was granted 534,400 options; and
- Jonathan Allis was granted 534,400 under a separate option grant.

Kenneth West's pre-2018 options have an exercise price of US\$0.0337. They were issued on 16 December 2015 and expire on 16 December 2025. 400,800 of Bastiaan Driehuys' options with an exercise price of US\$0.00412 were issued on 15 December 2014 and expire on 15 December 2024 and 400,800 options with an exercise price of US\$0.0337 were issued on 16 December 2015 and expire on 16 December 2025.

#### Directors' beneficial interests in warrants to subscribe for additional shares of the Company:

	2018 Number	2017 Number
Richard Morgan	-	523,659
Robert Bertoldi	-	523,659
Bastiaan Driehuys	148,456	148,456

The warrants issued to Richard Morgan and Robert Bertoldi are part of the Amphion Warrants. They had an exercise price of £0.009. The warrants expired on 31 May 2018 as the Company did not raise a minimum of \$5 million at £0.25 on or before 31 May 2018. The warrants issued to Bastiaan Driehuys have an exercise price of US\$0.00037. The warrant holdings noted above include those shares held by connected persons of the individual director.

#### continued

The options and warrants holdings noted above include those shares held by connected persons of the individual director.

### Common, Options and Warrant Shares:

(On a fully-diluted basis)	Number of shares at 31 December 2018	% held at 31 December 2018	Number of shares at 20 June 2019	% held at 20 June 2019
Richard Morgan	419,018	0.4	419,018	0.4
Richard Hullihen	2,137,354	2.1	2,137,354	2.1
Kenneth West	475,594	0.5	475,594	0.5
Bastiaan Driehuys	12,267,503	12.2	12,267,503	12.2
Robert Bertoldi	93,333	0.1	93,333	0.1

Note: February 2018, the Company declared a share sub-division of 26.72:1.

#### Share option schemes

In order to provide incentive for the management and key employees of the Group, the Company awards stock options. The Directors defined a new plan in 2018 and implemented it. The existing options granted prior to the merger were converted to options in Polarean Imaging, Plc.

### **Substantial Shareholders**

As well as the Directors' interests reported above, the following interests of 3.0% and above as at the date of this report were as follows at 31 December 2018 (on a fully-diluted basis):

	Number of shares, options or warrants	% held
Amphion Innovations plc	18,372,524	18.2
Bastiaan Driehuys	12,267,503	12.2
NUKEM Isotopes Imaging GmbH	11,234,208	11.2
W.B. Nominees Limited	8,736,697	8.7
Amati Global Investors	8,571,429	8.5
John Sudol	6,206,121	6.2
David & Monique Newlands	3,052,000	3.03

Note: February 2018, the Company declared a share sub-division of 26.72:1.

### **Corporate Responsibility**

The Board recognises its employment, environmental and health and safety responsibilities. It devotes appropriate resources towards monitoring and improving compliance with existing standards. The Executive Directors are responsible for these areas at Board level, ensuring that the Group's policies are upheld and providing the necessary resources.

### **Employees**

The Group is committed to achieving equal opportunities and to complying with relevant anti-discrimination legislation. It is established Group policy to offer employees and job applicants the opportunity to benefit from fair employment, without regard to their sex, sexual orientation, marital status, race, religion or belief, age or disability. Employees are encouraged to train and develop their careers.

The Group has continued its policy of informing all employees of matters of concern to them as employees, both in their immediate work situation and in the wider context of the Group's well-being. Communication with employees is affected through the Board, the Group's management briefings structure, formal and informal meetings and through the Group's information systems.

#### continued

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

Company law requires the directors to prepare financial statements for each financial year. Under that law the directors have elected to prepare the financial statements in accordance with International Financial Reporting Standards (IFRSs') as adopted by the EU and applicable law.

Under company law the directors must not approve the financial statements unless they are satisfied that they give a true and fair view of the state of affairs of the Company and the Group and of the profit or loss of the Group for that period. In preparing these financial statements, the directors are required to:

- select suitable accounting policies and then apply them consistently;
- · make judgements and accounting estimates that are reasonable and prudent;
- state whether applicable accounting standards have been followed, subject to any material departures disclosed and explained in the financial statements;
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the Group will continue in business.

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

They are further responsible for ensuring that the Strategic Report and the Directors' Report and other information included in the Annual Report and Financial Statements is prepared in accordance with applicable law in the United Kingdom.

The maintenance and integrity of the Polarean Imaging plc web site is the responsibility of the directors; the work carried out by the auditors does not involve the consideration of these matters and, accordingly, the auditors accept no responsibility for any changes that may have occurred in the accounts since they were initially presented on the website. Legislation in the United Kingdom governing the preparation and dissemination of the accounts and the other information included in annual reports may differ from legislation in other jurisdictions.

### **Auditors**

Each of the persons who are directors at the time when this Directors' report is approved has confirmed that:

- so far as that director is aware, there is no relevant audit information of which the Group and the Group's auditor is unaware; and
- that director has taken all the steps that ought to have been taken as a director in order to be aware of
  any relevant audit information and to establish that the Company and the Group's auditor is aware of
  that information.

Crowe U.K. LLP has expressed its willingness to continue in office and a resolution to re appoint the firm as Auditor and authorising the Directors to set their remuneration will be proposed at the forthcoming Annual General Meeting.

Richard Morgan Non-Executive Chairman

26 June 2019

### Corporate Governance Statement for the year ended 31 December 2018

As Chairman of the Board of Directors of Polarean Imaging Plc (Polarean, or the Company/Group as the context requires), it is my responsibility to ensure that Polarean has both sound corporate governance and an effective Board. As Chairman of the Company, my responsibilities include leading the Board effectively, overseeing the Company's corporate governance model, communicating with shareholders, and ensuring that good information flows freely between the Executive and Non-Executives Directors in a timely manner. My leadership of the Board is undertaken in a manner which ensures that the Board retains integrity and effectiveness and includes creating the right Board dynamic and ensuring that all important matters, in particular strategic decisions, receive adequate time and attention at Board meetings.

It is the Board's job to ensure that Polarean is managed for the long-term benefit of all shareholders, with effective and efficient decision-making. Corporate governance is an important part of that role, reducing risk and adding value to our business.

The Directors of Polarean recognise the value of good corporate governance in every part of its business. As Polarean is an AIM listed company, it is required to adopt a recognised corporate governance code and disclose how it complies with that code and, to the extent Polarean departs from the corporate governance provisions outlined by that code, it must explain its reasons for doing so. The Directors have adopted the requirements of the Quoted Companies Alliance's Corporate Governance Code for Small and Mid-Size Quoted Companies (the "QCA Code"), to the extent that they consider it appropriate having regard to the Company's size, board structure, stage of development and resources. The Board considers that compliance with the QCA Code will enable us to serve the interests of all our key stakeholders, including our shareholders, and will promote the maintenance and creation of long-term value in the Company. This report describes our approach to governance, including information on relevant policies, practices and the operation of the Board and its Committees. Additional detail on how the company has applied the QCA code is also provided in the corporate governance section of our website http://www.polarean-ir.com/content/investors/governance.asp. Any areas of non-compliance with the QCA Code are also explained.

Polarean seeks to constantly improve its corporate governance practices. Prior to the Company listing in March 2018, the Company implemented certain governance related measures including the formation of the Company's Audit and Remuneration Committees, and the adoption of a Share Dealing Code.

### Strategy, Risk Management and Responsibility

A description of the Company's business model and strategy can be found on pages 7-14 in the Strategic Report, and the key challenges in their execution can be found on pages 12-14 under "Principal Risks and Uncertainties".

The Board is responsible for the monitoring of financial performance against budget and forecast and the formulation of the Group's risk appetite including the identification, assessment and monitoring of Polarean's principal risks. The Board recognises the need for an effective and well-defined risk management process and it oversees and regularly reviews the current risk management and internal control mechanisms.

The Board has overall responsibility for identifying, monitoring and reviewing the Company's risks, and assessing the systems of external control for effectiveness. The Executive Directors report any new or changed risks, and any changes in risk management/control to the Board. The Board discusses all business matters having regard to the risks for the Group and to the extent that risks inherent in a particular activity are considered significant, appropriate action is taken and steps taken to mitigate the issue. The overall objective of the Board is to set policies that seek to reduce risk as far as possible without unduly affecting the Company's competitiveness and flexibility.

The Board is satisfied that the procedures in place meet the particular needs of the Group in managing the risks to which it is exposed. The Board is satisfied with the effectiveness of the system of internal controls, but by their very nature, these procedures can provide reasonable, not absolute, assurance against material missta tement or loss. The Board has delegated responsibility to the Audit Committee for ensuring that the Company's management reviews, monitors and reports on the integrity of the consolidated financial statements of the Company and related financial information. The Audit Committee will maintain effective working relationships with the Board of Directors and executive management, and the external auditors and will monitor the independence and effectiveness of the auditors and the audit. The Company has strict segregation of duties and authority controls which are reviewed annually by the auditors whom report their findings to the Audit Committee.

The Board has reviewed the need for an internal audit function and has decided that, given the nature of the Group's business and assets and the overall size of the Group, the systems and procedures currently employed provide sufficient assurance that a sound system of internal controls are in place, which safeguards the shareholders' investment and the Group's assets. An internal audit function is therefore considered unnecessary. However, the Board will continue to monitor the need for this function.

#### Continued

The Board is responsible for the Group's system of internal control and for reviewing its effectiveness. Such a system is designed to manage rather than eliminate risk of failure to achieve the business objectives and can only provide reasonable and not absolute assurance against material misstatement or loss. The Company's current system of internal financial control comprises those controls established to provide reasonable assurance of:

- The safeguarding of assets against unauthorised use or disposal; and
- The maintenance of proper accounting records and the reliability of financial information used within the business and for publication

The key procedures of internal financial control of the Group are as follows:

- The Board reviews and approves budgets and monitors performance against those budgets on a monthly basis.
- The Group has clearly defined reporting and authorisation procedures relating to the key financial areas.

### The Board

The Group is run by the Board of Directors, which comprises three Executive Directors and four Non-Executive Directors. As the business grows and becomes more complex it is anticipated that the Board will be added to. In addition, the Group has a Chief Financial Officer, Charles Osborne and a Company Secretary, Stephen Austin.

The Board meets regularly and is responsible for the Group's corporate strategy, monitoring financial performance, approval of capital expenditure, treasury and risk management policies. Board papers are sent out to all Directors in advance of each Board meeting including management accounts and accompanying reports from those responsible.

At the date of this Report, the Board has seven members, whose roles are set out below:

Director's Name	Position(s)
Richard Morgan	Non-Executive Chairman, Chairman of the Remuneration Committee & member of the Audit Committee
Richard Hullihen	Executive Director – Chief Executive Officer
Kenneth West	Executive Director – Chief Operating Officer
Bastiaan Driehuys	Executive Director – Chief Technology Officer & member of Remuneration Committee
Robert Bertoldi	Non-Executive Director & Chairman of the Audit Committee,
Jonathan Allis	Independent Non-Executive Director
Juergen Laucht	Non-Executive Director & member of Remuneration and Audit Committees

The biographical details of the Directors of the Company are set out on the Company's website: http://www.polarean-ir.com/content/investors/board.asp

The Directors believe that the Board, as a whole, has a broad range of commercial and professional skills, enabling it to discharge its duties and responsibilities effectively and that the Non-Executive Directors, together, have a sufficient range of experience and skills to enable them to provide the necessary guidance, oversight and advice for the Board to operate effectively. All Directors are encouraged to use their independent judgement and to challenge all matters, whether strategic or operational.

Jonathan Allis is currently the Company's only independent Non-Executive Director. The Company acknowledges that the guidance in the QCA Code is for a company to have at least two independent Non-Executive Directors. However, the Directors are satisfied that the Company's board composition is appropriate given the Company's size and stage of development. All Directors are encouraged to use their independent judgement and to challenge all matters, whether strategic or operational. The Directors shall keep the position under regular review and to the extent additional independence is felt to be required on the Board, it shall be sought.

The Board will seek to take into account any Board imbalances for future nominations. The Company is committed to a culture of equal opportunities for all employees regardless of gender. The Board aims to be diverse in terms of its range of culture, nationality and international experience. Given the current phase of Polarean's life cycle, the Board has determined that it is not practicable to set measurable objectives for achieving gender diversity. It is the Board's intention as the size and complexity of the Company grows, to set and aim to achieve gender diversity objectives pursuant to a defined diversity policy.

#### Continued

All of the Executive Directors work full time for the Company. The Chairman is expected to devote not less than 52 days per annum and the Non-Executive Directors are each expected to dedicate not less than 15 days per annum to the Company's affairs. The Chairman and other Non-Executive Directors endeavour to ensure that their knowledge of best practices and regulatory developments is continually up to date by attending relevant seminars and conferences.

There were 16 scheduled board meetings held during 2018. The table below sets out attendance statistics for each Director at Board and, where relevant, Committee meetings held during the financial year.

Director	Board (16 meetings held)	Audit Committee (2 meetings held)	Remuneration Committee (2 meetings held)
Richard Morgan	16/16	2/2	2/2
Richard Hullihen	16/16	-	-
Kenneth West	16/16	-	-
Bastiaan Driehuys	13/16	-	2/2
Robert Bertoldi	16/16	2/2	-
Jonathan Allis	9/16		-
Juergen Laucht	16/16	2/2	2/2

The Board, as a whole, is responsible for the overall management of the Group and for its strategic direction, including approval of the Group's strategy, its annual business plans and budgets, the interim and full year financial statements and reports, any dividend proposals, the accounting policies, major capital projects, any investments or disposals, its succession plans and the monitoring of financial performance against budget and forecast and the formulation of the Group's risk appetite including the identification, assessment and monitoring of Polarean's principal risks. In accordance with best practice, Polarean has adopted a formal schedule of Matters Reserved for the Board. These are reviewed annually, and any items not included within the schedule are delegated to the management team.

In order to keep Director skillsets up to date, the Board uses third parties to advise the Directors of their responsibilities including receiving advice from the Company's external lawyers. The Board proposes to introduce a facility for Directors to receive training on relevant developments on a more regular basis. The Board reviews the appropriateness and opportunity for continuing professional development in order to keep each Director's skillset up-to-date. In addition to their general Board responsibilities, Non-Executive Directors are encouraged to be involved in specific workshops or meetings, in line with their individual areas of expertise. The Board shall review annually the appropriateness and opportunity for continuing professional development, whether formal or informal.

Polarean's Company Secretary, Stephen Austin, is responsible for ensuring that Board procedures are followed and that the Company complies with all applicable rules, regulations and obligations governing its operation, as well as helping the Chairman maintain excellent standards of corporate governance. There are processes in place enabling Directors to take independent advice at the Company's expense in the furtherance of their duties, and to have access to the advice and services of the Company Secretary.

#### **Board Committees**

The Board has established an Audit Committee and a Remuneration Committee with delegated duties and responsibilities.

### **Audit Committee**

Robert Bertoldi, Non-Executive Director, is Chairman of the Audit Committee. The other members of the Committee are Richard Morgan and Juergen Laucht. The Audit Committee is responsible for ensuring that the financial performance, position and prospects for the Group are properly monitored, controlled and reported on and for meeting the auditors and reviewing their reports relating to accounts and internal controls. The Committee held 2 meetings during the year. A report by the Chairman of the Audit Committee is included on page 27.

### Remuneration Committee

Richard Morgan, Non-Executive Director, is Chairman of the Remuneration Committee. The other members of the Committee are Bastiaan Driehuys and Juergen Laucht. The Remuneration Committee is responsible for reviewing performance of Executive Directors and determining the remuneration and basis of service agreements. The Remuneration Committee also determines the payment of any bonuses to Executive Directors and the grant of options. A report by the Chairman of the Remuneration Committee is included on page 25.

Continued

#### **Nomination Committee**

The Company does not currently have a Nomination Committee, as the Board does not consider it appropriate to establish such a committee at this stage of the Company's development. Decisions which would usually be taken by the nomination committee will be taken by the Board as a whole. The Board as a whole will also be responsible for AIM compliance.

The Chairman and the Board continue to monitor and evolve the Company's corporate governance structures and processes, and maintain that these will evolve over time, in line with the Company's growth and development.

#### Advisers

The Board has regular contact with its advisers to ensure that it is aware of changes to generally accepted corporate governance procedures and requirements and that the Group remains, at all times, compliant with applicable rules and regulations. The Company holds appropriate insurance cover in respect of possible legal action against its Directors. The Company's Nomad supports the Board's development, specifically providing guidance on corporate governance and other regulatory matters, as required.

All Directors may receive independent professional advice at Polarean's expense, if necessary, for the performance of their duties.

#### **Board Performance Evaluation**

The structure of the Board is subject to continual review to ensure that it is appropriate for the Company. Over the next 12 months the Company intends to review the performance of the Board as a whole to ensure that its members collectively function in an efficient manner, focusing more closely on defined objectives and targets for improving performance, as well as reviewing the effectiveness of each Committee.

The Directors consider that the Company and Board are not yet of sufficient size for a full Board performance evaluation to make commercial and practical sense at the current time, although the Board currently runs a self-evaluation process whereby the Chairman annually assesses the individual contributions of each of the members of the team to ensure that:

- Their contribution is relevant and effective;
- That they are committed; and
- Where relevant, they have maintained their independence.

Therefore, the Board accepts that the Company does not comply with this aspect of the QCA Code, although frequent Board meetings/calls, the Directors discuss areas where they feel a change would be beneficial for the Company, and the Company Secretary remains on hand to provide advice. As the Company grows, it intends to expand the Board and, with expansion, re-consider the need for a formal Board evaluation.

The Company has not yet adopted a policy on succession planning, in particular with regard to the Company's Chairman, Richard Morgan. The Company will consider succession planning in respect of the Board and other members of senior management as appropriate, as part of its review of Board effectiveness over the next 12 months.

### Culture

The Board recognises that its decisions regarding strategy and risk may impact the corporate culture of the Company as a whole and that this will impact the performance of the Company. It is aware that the tone set by the Board and by its decisions regarding strategy and risk may impact the corporate culture of the Company as a whole and on the way that employees and other stakeholders behave.

The Company operates in a manner that encourages an open and respectful dialogue with employees, customers and other stakeholders and the Board considers that sound ethical values and behaviours are crucial to the ability of the Company to achieve its corporate objectives. The Group is committed to the highest standards of personal and professional ethical behavior, and this must be reflected in every aspect of the way in which the Company operates. The Board places great importance on this aspect of corporate life and seeks to ensure that this flows through all that the Company does. The Directors believe that the Company has an open culture facilitating comprehensive dialogue and feedback and enabling positive and constructive challenge.

The Directors consider that at present the Group has an open culture facilitating comprehensive dialogue and feedback and enabling positive and constructive challenge. The Executive Directors regularly meet with senior management and discuss staff well-being, development and staff feedback. Employees are encouraged to engage directly with Directors, and the Group seeks to promote Group values and behavior through a top-down approach.

Continued

### **Anti-Bribery Policy**

The Group has in place appropriate guidance, training and implementation of procedures to ensure compliance with the UK Bribery Act. The Group takes a zero-tolerance approach to bribery and corruption and we are committed to act professionally, fairly and with integrity in all our business dealings. Any breach of this policy will be regarded as a serious matter by the Company and is likely to result in disciplinary action and potentially the involvement of the police.

#### **Share Dealing**

The Group has a Share Dealing Code, which will apply to any person discharging management responsibility, including the Directors and members of the senior management team and any closely associated persons and applicable employees.

The Share Dealing Code imposes restrictions beyond those that are imposed by law (including by FSMA and the Market Abuse Regulation (EU) No.596/2014 and other relevant legislation) and its purpose is to ensure that persons discharging managerial responsibility and persons connected with them do not abuse, and do not place themselves under suspicion of abusing, price-sensitive information that they may have or be thought to have, especially in periods leading up to an announcement of both financial results and the results of the Group's clinical trials. The Share Dealing Code sets out a notification procedure which is required to be followed prior to any dealing in the Company's securities.

#### **Communication with Shareholders**

The Group is strongly committed to the maintenance of good investor relations and seeks, wherever possible to be a relationship of mutual understanding with both its institutional and private client investors. Additionally, the Board seeks to meet with shareholders whenever possible and to use the Group's website www.polarean.com to communicate with all shareholders. The board also welcomes shareholders' enquiries, which may also be sent via the Group's website.

The corporate governance arrangements that the Board has adopted are designed to ensure that the Company delivers long-term value to its shareholders and that shareholders are able to express their views and expectations for the Company in a manner that encourages open dialogue with the Board.

In addition to the publication of half-year and full year results statements, the Company provides frequent trading updates and makes its senior management team available to meet with shareholders, when there is opportunity for shareholders to voice their concerns, thoughts or needs. The Company has recently appointed an independent research company to publish reports on the Company, in order that more of its shareholders may obtain access to such information.

# **Remuneration Committee Report**

### Dear Shareholder

As the Chairman of Polarean's Remuneration Committee, I present my first Remuneration Committee Report for the year ended 31 December 2018, which has been prepared by the Committee and approved by the Board.

The Remuneration Committee is responsible for determining the remuneration policy for the Executive Directors, and for overseeing the Company's long-term incentive plans. The Board as a whole is responsible for determining Non-Executive Directors' remuneration.

The Committee will continue to monitor market trends and developments in order to assess those relevant for the Group's future remuneration policy.

### Remuneration policy for 2018 and future years

The Remuneration Committee determines the Company's policy on the structure of Executive Directors' and if required, senior management's remuneration. The objectives of this policy are to:

- Reward Executive Directors and senior management in a manner that ensures that they are properly incentivised and motivated to perform in the best interests of shareholders.
- Provide a level of remuneration required to attract and motivate high-calibre Executive Directors and senior management of appropriate calibre.
- Encourage value creation through consistent and transparent alignment of incentive arrangements with the agreed company strategy over the long term.
- Ensure the total remuneration packages awarded to Executive Directors, comprising both performance-related and non-performance-related remuneration, is designed to motivate the individual, align interests with shareholders and comply with corporate governance best practice.

#### **Objectives and Responsibilities**

The Remuneration Committee's main responsibilities can be summarised as follows:

- To determine the framework or broad policy for the remuneration of the Chairman, the Executive Directors, and such other senior executives as it is requested by the Board to consider. The remuneration of Non-Executive Directors shall be a matter for the Chairman and the Executive Directors of the Board. No Director shall be involved in any decisions as to their own remuneration;
- To determine such remuneration policy, taking into account all factors which it deems necessary (including relevant legal and regulatory requirements);
- To review the ongoing appropriateness and relevance of the remuneration policy, including policy comparisons with market competitors;
- To design and determine targets for any performance related pay schemes operated by the Company and approving the total annual payments made under such schemes;
- To review the design of, and any changes to, all share incentive plans;
- To advise on any major changes in employee benefits structures throughout the Company;
- To review the structure, size and composition of the Board, including the skills, knowledge and experience;
- To give full consideration to succession planning;
- · To recommend new Board appointments; and
- To consider any matter specifically referred to the Committee by the Board.

## **Remuneration Policy for Non-Executive Directors**

Jonathan Allis, Juergen Laucht, Robert Bertoldi and I each receive a fee for our services as Directors, which is approved by the Board, mindful of the time commitment and responsibilities of our roles and of current market rates for comparable organisations and appointments.

# **Remuneration Committee Report**

Continued

### Remuneration decisions for 2018

Bonuses payable for the year ended 31 December 2018 was US\$nil (2017: US\$nil).

### **Remuneration Committee Effectiveness**

The Committee is due to perform a self-assessment of its effectiveness during the second half of 2019.

Further information on Directors' remuneration, including Directors' emoluments, share options and warrants holdings can be found in the Directors' Report on pages 16-18.

**Richard Morgan**Chairman of the Remuneration Committee
26 June 2019

### **Audit Committee Report**

#### Dear Shareholder

As the Chairman of Polarean's Audit Committee, I present my first Audit Committee Report for the year ended 31 December 2018, which has been prepared by the Committee and approved by the Board.

The Committee is responsible for reviewing and reporting to the Board on financial reporting, internal control and risk management, and for reviewing the performance, independence and effectiveness of the external auditors in carrying out the statutory audit.

During the year, the Committee's primary activity involved meeting with the external auditors, considering material issues and areas of judgement, and reviewing and approving the interim and year end results and accounts.

In addition, the Committee reviewed the audit provided by Crowe UK LLP, the Group's external auditors. The Committee concluded that Crowe UK LLP are delivering the necessary audit scrutiny.

Accordingly, the Committee recommended to the Board that Crowe UK LLP be re-appointed for the next financial year.

#### During 2018, the Committee:

- met with the external auditors to review and approve the annual audit plan and receive their findings and report on the annual audit;
- considered significant issues and areas of judgement with the potential to have a material impact on the financial statements;
- considered the integrity of the published financial information and whether the Annual Report and Accounts
  taken as a whole are fair, balanced and understandable and provide the information necessary to assess the
  Group's position and performance, business model and strategy; and
- reviewed and approved the interim and year end results and accounts.

In the coming year, in addition to the Committee's ongoing duties, the Committee will:

- consider significant issues and areas of judgement with the potential to have a material impact on the financial statements; and
- keep the need for an internal audit function under review, having regard to the Company's strategy and resources.

### **Audit Committee Effectiveness**

The Committee is due to perform an assessment of its effectiveness during the second half of 2019.

Robert Bertoldi Chairman of the Audit Committee 26 June 2019

# Independent Auditors' report to the members of

# Polarean Imaging plc

#### Opinion

We have audited the financial statements of Polarean Imaging plc (the "Parent Company") and its subsidiaries (the "Group") for the year ended 31 December 2018, which comprise:

- the Group statement of comprehensive income for the year ended 31 December 2018;
- the Group and parent company statements of financial position as at 31 December 2018;
- the Group and parent company statements of cash flows for the year then ended;
- · the Group and parent company statements of changes in equity for the year then ended; and
- the notes to the financial statements, including a summary of significant accounting policies.

The financial reporting framework that has been applied in the preparation of the financial statements is applicable law and International Financial Reporting Standards (IFRSs) as adopted by the European Union.

In our opinion:

- the financial statements give a true and fair view of the state of the Group's and of the Parent Company's affairs as at 31 December 2018 and of the Group's loss for the period then ended;
- the group financial statements have been properly prepared in accordance with IFRSs as adopted by the European Union:
- the parent company financial statements have been properly prepared in accordance with IFRSs as adopted by the European Union as applied in accordance with the provisions of the Companies Act 2006; and
- the financial statements have been prepared in accordance with the requirements of the Companies Act 2006.

### **Basis for opinion**

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

### Conclusions relating to going concern

We have nothing to report in respect of the following matters in relation to which ISAs (UK) require us to report to you when:

- The directors' use of the going concern basis of accounting in the preparation of the financial statements is not appropriate; or
- The directors have not disclosed in the financial statements any identified material uncertainties that may cast
  significant doubt about the Group's or the parent company's ability to continue to adopt the going concern basis of
  accounting for a period of at least twelve months from the date when the financial statements are authorised for
  issue.

### Overview of our audit approach

### Materiality

In planning and performing our audit we applied the concept of materiality. An item is considered material if it could reasonably be expected to change the economic decisions of a user of the financial statements. We used the concept of materiality to both focus our testing and to evaluate the impact of misstatements identified. Based on our professional judgement, we determined overall materiality for the Group financial statements as a whole to be US\$250,000, which represents approximately 5% of the Group's operating loss. We use a different level of materiality ('performance materiality') to determine the extent of our testing for the audit of the financial statements. Performance materiality is set based on the audit materiality as adjusted for the judgements made as to the entity risk and our evaluation of the specific risk of each audit area having regard to the internal control environment.

Where considered appropriate performance materiality may be reduced to a lower level, such as, for related party transactions and directors' remuneration.

# Independent Auditors' report to the members of

# Polarean Imaging plc

#### continued

We agreed with the Audit Committee to report to it all identified errors in excess of US\$6,000. Errors below that threshold would also be reported to it if, in our opinion as auditor, disclosure was required on qualitative grounds.

### Overview of the scope of our audit

Polarean Imaging plc and its subsidiaries are accounted for from one operating location in North Carolina, USA. Our audit was conducted from this location and all Subsidiary companies were within the scope of our audit testing.

#### **Key Audit Matters**

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the financial statements of the current period and include the most significant assessed risks of material misstatement (whether or not due to fraud) that we identified. These matters included those which had the greatest effect on: the overall audit strategy, the allocation of resources in the audit; and directing the efforts of the engagement team. These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

This is not a complete list of all risks identified by our audit.

#### Key audit matter

# How the scope of our audit addressed the key audit matter

### Revenue recognition

Revenue is a significant figure in these financial statements and is generated from various streams.

Our audit risk focuses on the risk that revenues may be overstated to meet market expectations. We specifically identified risks that either revenue transactions recorded in the year may not exist (the risk of fictitious revenue transactions) or that revenues transactions recorded in the year may not have been despatched to the customer before year end and therefore may have been recorded in the incorrect period.

The accounting policy is documented in note 3

We designed procedures to test each revenue stream and considered whether the revenue recognition policy applied to the revenue stream was appropriate. Our testing in this area included agreeing that revenue was appropriately recognised. This included cut off procedures.

Our audit procedures in relation to the above matter was designed in the context of our audit opinion as a whole. They were not designed to enable us to express an opinion on these matters individually and we express no such opinion.

### Other information

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

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated. If we identify such material inconsistencies or apparent material misstatements, we are required to determine whether there is a material misstatement in the financial statements or a material misstatement of the other information. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact.

We have nothing to report in this regard.

### Opinion on other matter prescribed by the Companies Act 2006

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

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

# Independent Auditors' report to the members of

# Polarean Imaging plc

continued

### Matters on which we are required to report by exception

In light of the knowledge and understanding of the group and the parent company and their environment obtained in the course of the audit, we have not identified material misstatements in the strategic report or the directors' report.

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

- adequate accounting records have not been kept by the parent company, or returns adequate for our audit
  have not been received from branches not visited by us; or
- the parent company financial statements are not in agreement with the accounting records and returns; or
- certain disclosures of directors' remuneration specified by law are not made; or
- we have not received all the information and explanations we require for our audit.

#### Responsibilities of the directors for the financial statements

As explained more fully in the directors' responsibilities statement set out on page 19, the directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view, and for such internal control as the directors determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

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

### Auditor's responsibilities for the audit of the financial statements

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

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

### Use of our report

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

Stephen Bullock (Senior Statutory Auditor) for and on behalf of Crowe U.K. LLP Statutory Auditor London

26 June 2019

# **Consolidated Statement of Comprehensive Income**

for the year ended 31 December 2018

		2018	2017
_	Notes	US\$	US\$
Revenue	4	2,439,139	1,237,163
Cost of sales		(633,463)	(297,215)
Gross profit		1,805,676	939,948
Administrative expenses		(6,161,916)	(4,051,000)
Depreciation	11	(10,140)	(7,478)
Amortisation	12	(616,852)	(361,746)
Selling and distribution expenses		(31,766)	(28,752)
Share-based payment expense	19	(251,790)	(414,866)
Total administrative expenses		(7,072,464)	(4,863,842)
Operating loss	6	(5,266,788)	(3,923,894)
Finance income	7	184	129
Finance expense	7	(188,055)	(34,056)
Loss before tax		(5,454,659)	(3,957,821)
Taxation	10	-	-
Loss for the year and total other comprehensive expense		(5,454,659)	(3,957,821)
Loss per share			
Basic and diluted (US\$)	9	(0.078)	(0.139)

The results reflected above relate to continuing activities.

There is no recognised income or expense 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**

20 2	t 31	December	2018

a	s at 31 December 2018		
	Notes	2018	2017
ASSETS		US\$	US\$
Non-current assets			
Property, plant and equipment	11	17,752	21,341
Intangible assets	12	4,044,398	4,661,250
Trade and other receivables	14	12,539	12,539
		4,074,689	4,695,130
Current assets			
Inventories	15	651,781	649,860
Trade and other receivables	14	4,226,585	488,861
Cash and cash equivalents	16	875,601	960,217
		5,753,967	2,098,938
TOTAL ASSETS		9,828,656	6,794,068
Equity attributable to holders of the parent Share capital Share premium Group re-organisation reserve	17 18 18	49,427 11,063,075 7,813,337	23,291 1,448,037 7,813,337
Other equity	18		87,305
Share-based payment reserve Accumulated losses	19 18	1,078,335	826,545
Accumulated losses	18	(12,212,767) 7,791,407	(6,758,108)
Non-current liabilities			
Provision for contingent consideration	20	316,000	316,000
Deferred income	21	70,726	-
		386,726	316,000
Current liabilities			
Trade and other payables	22	1,590,482	1,906,376
Borrowings	23	5,213	1,104,723
Deferred income	21	54,828	26,562
		1,650,523	3,037,661
TOTAL EQUITY AND LIABILITIES		9,828,656	6,794,068

These Financial Statements were approved and authorised for issue by the Board of Directors on 26 June 2019 and were signed on its behalf by:

# **Richard Morgan**

Non-Executive Chairman

# **Company Statement of Financial Position**

as at 31 December 2018 **Notes** 2018 2017 US\$ US\$ **ASSETS** Non-current assets Investment in subsidiary 13 4,342,848 4,342,848 4,342,848 4,342,848 **Current assets** Trade and other receivables 14 9,370,611 1,891,495 Cash and cash equivalents 16 235,766 23,106 9,606,377 1,914,601 **TOTAL ASSETS** 6,257,449 13,949,225 **EQUITY AND LIABILITIES** Equity attributable to holders of the parent Share capital 17 49,427 23,291 Share premium 11,063,075 1,448,037 18 4,322,527 Merger reserve 18 4,322,527 Other equity 87,305 18 Share-based payment reserve 19 773,304 521,514 Accumulated losses 18 (2,287,282)(956,714)13,921,051 5,445,960 **Current liabilities** 28,174 Trade and other payables 22 25,742 Borrowings 23 785,747 28,174 811,489 **TOTAL EQUITY AND LIABILITIES** 13,949,225 6,257,449

The loss for the financial year dealt with in the financial statements of the parent Company was US\$1,330,568 (2017: US\$956,714).

These Financial Statements were approved and authorised for issue by the Board of Directors on 26 June 2019 and were signed on its behalf by:

### **Richard Morgan**

Non-Executive Chairman

# **Consolidated Statement of Changes in Equity**

for the year ended 31 December 2018

	Share capital US\$	Share premium US\$	Other equity US\$	Share-based payment reserve US\$	Group re-org reserve US\$	Accumulated losses US\$	Total equity US\$
As at 1 January 2017	1	-	-	238,172	1,976,367	(2,800,287)	(585,747)
Comprehensive income							
Loss for the year	-	-	-	-	-	(3,957,821)	(3,957,821)
Transactions with owners							
Issue of shares	2,970	1,982,094	-	-	-	-	1,985,064
Share issue costs	-	(534,057)	-	173,507	-	-	(360,550)
Share-based payment expense	-	-	-	414,866	-	-	414,866
Group re-organisation	20,320	-	-	-	5,836,970	-	5,857,290
Convertible loans	-	-	87,305	-	-	-	87,305
As at 31 December 2017	23,291	1,448,037	87,305	826,545	7,813,337	(6,758,108)	3,440,407
Comprehensive income							
Loss for the year	-	-	-	-	-	(5,454,659)	(5,454,659)
Transactions with owners							
Issue of shares	26,136	10,161,474	(87,305)	-	-	-	10,100,305
Share issue costs	-	(546,436)	-	-	-	-	(546,436)
Share-based payment expense	-	-	-	251,790		-	251,790
As at 31 December 2018	49,427	11,063,075	-	1,078,335	7,813,337	(12,212,767)	7,791,407

# **Company Statement of Changes in Equity**

for the year ended 31 December 2018

	Share capital US\$	Share premium US\$	Other equity US\$	Share-based payment reserve US\$	Merger reserve US\$	Accumulated losses US\$	Total equity US\$
As at 1 January 2017	1	-	-	-	-	-	1
Comprehensive income							
Loss for the year	-	-	-	-	-	(956,714)	(956,714)
Transactions with owners							
Issue of shares	23,290	1,982,094	-	-	4,322,527	-	6,327,911
Share issue costs	-	(534,057)	-	173,507	-	-	(360,550)
Share-based payment expense	-	-	-	348,007	-	-	348,007
Convertible loans	-	-	87,305	-	-	-	87,305
As at 31 December 2017	23,291	1,448,037	87,305	521,514	4,322,527	(956,714)	5,445,960
Comprehensive income							
Loss for the year	-	-	-	-	-	(1,330,568)	(1,330,568)
Transactions with owners							
Issue of shares	26,136	10,161,474	(87,305)	-	-	-	10,100,305
Share issue costs	-	(546,436)	-	-	-	-	(546,436)
Share-based payment expense	-	<u>-</u>	-	251,790	-	-	251,790
As at 31 December 2018	49,427	11,063,075	-	773,304	4,322,527	(2,287,282)	13,921,051

# **Consolidated Statement of Cash Flows**

for the year ended 31 December 2018

	2018 US\$	2017 US\$
Cash flows from operating activities		
Loss before tax	(5,454,659)	(3,957,821)
Adjustments for non-cash/non-operating items:		
Depreciation of plant and equipment	10,140	7,478
Amortisation of intangible assets	616,852	361,746
Share-based payment expense	251,790	414,866
Interest paid	188,055	34,056
Interest received	(184)	(129)
Operating cash flows before movements in working capital	(4,388,006)	(3,139,804)
Increase in inventories	(1,921)	(328,199)
Increase in trade and other receivables	(69,517)	(440,931)
(Decrease)/increase in trade and other payables	(315,894)	1,343,861
Increase/(decrease) in deferred income	98,992	(50,618)
Net cash used in operations	(4,676,346)	(2,615,691)
Cash flows from investing activities		
Purchase of plant and equipment	(6,551)	(16,834)
Interest received	184	129
Net cash used in investing activities	(6,367)	(16,705)
Cash flows from financing activities		
Issue of shares	5,093,775	2,481,808
Interest paid	(188,055)	(34,056)
Issue of notes and loans	5,213	1,047,014
Repayment of notes and loans	(312,836)	-
Net cash generated by financing activities	4,598,097	3,494,766
Net (decrease)/increase in cash and cash equivalents	(84,616)	862,370
Cash and cash equivalents at the beginning of year	960,217	97,847
Cash and cash equivalents at end of year	875,601	960,217

# **Company Statement of Cash Flows**

for the year ended 31 December 2018

	Year ended 31 December 2018 US\$	Year ended 31 December 2017 US\$
Cash flows from operating activities		
Loss before tax	(1,330,568)	(956,714)
Adjustments for non-cash/non-operating items:		
Share-based payment expense	251,790	348,007
Operating cash flows before movements in working capital	(1,078,778)	(608,707)
Increase in trade and other payables	2,433	25,742
Net cash used by operations	(1,076,345)	(582,965)
Cash flows from financing activities		
Issue of shares	5,099,914	1,624,514
Loans to intercompany	(3,810,909)	(1,851,022)
Issue of notes and loans	-	832,579
Net cash generated by financing activities	1,289,005	606,071
Increase in cash and cash equivalents	212,660	23,106
Cash and cash equivalents at the beginning of period	23,106	-
Cash and cash equivalents at end of period	235,766	23,106

The accompanying notes on pages 38 to 57 are an integral part of these financial statements.

### 1 General information

The Company is incorporated in England and Wales under the Companies Act 2006. The registered number is 10442853 and its registered office is at 27-28 Eastcastle Street, London, W1W 8DH. The Company is listed on AIM 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.

## 2 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.

### IFRS 9 'Financial Instruments'

IFRS 9 uses a single approach to determine whether a financial asset is measured at amortised cost or fair value, replacing the many different rules in IAS 39. The approach in IFRS 9 is based on how an entity manages its financial instruments (its business model) and the contractual cash flow characteristics of the financial assets. The Group has considered the implications of IFRS 9 to have an immaterial impact, as detailed in the financial assets accounting policy.

### IFRS 15 'Revenue from Contracts with Customers'

IFRS 15 is intended to clarify the principles of revenue recognition and establish a single framework for revenue recognition. This supersedes IAS 18 Revenue and the core principle is that an entity should recognise revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The Group has considered the implications of IFRS 15 to have an immaterial impact, as detailed in the revenue recognition accounting policy.

Certain other new standards and interpretations have been issued but are not expected to have a material impact on the Group's annual report and accounts.

## New and revised IFRS Standards in issue but not yet effective

At the date of authorisation of these financial statements, The Group has not applied the following new and revised IFRS Standards that have been issued but are not yet effective.

## IFRS 16 'Leases', effective 1 January 2019

The IASB has published IFRS 16 'Leases', completing its long-running project on lease accounting. The new Standard, which is effective for accounting periods beginning on or after 1 January 2019, requires lessees to account for leases 'on-balance sheet' by recognising a 'right-of-use' asset and a lease liability. The date of initial application of IFRS 16 for the Group will be 1 January 2019. It will affect most companies that report under IFRS and are involved in leasing and will have a substantial impact on the annual report and accounts of lessees of property and high value equipment. This standard has been endorsed by the European Union.

The Group's management has carried out an impact review of the implementation of IFRS 16 and has decided it will apply the modified retrospective adoption method in IFRS 16, and, therefore, will only recognise leases on the Statement of Financial Position as at 1 January 2019. In addition, it has decided to measure right-of-use assets by reference to the measurement of the lease liability on that date. This will ensure there is no immediate impact to net assets on that date.

At 31 December 2018 operating lease commitments amounted to US\$183,421 (see note 24), which is expected to reduce to US\$109,899 at 31 December 2019. Assuming the Group's lease commitments remain at this level, the effect of discounting those commitments is anticipated to result in right-of-use assets and lease liabilities of approximately US\$115,000 being recognised on 1 January 2019. However, further work still needs to be carried out to determine whether and when extension and termination options are likely to be exercised, which will result in the actual liability recognised being higher than this.

Instead of recognising an operating expense for its operating lease payments, the group will instead recognise interest on its lease liabilities and amortisation on its right-of-use assets. This will increase reported EBITDA by the amount of its current operating lease cost, which for the year ended 31 December 2018 was approximately US\$73,000.

There are no other standards issued which are expected to have a material impact on the financial statements.

Continued

## 3 Significant accounting policies

### **Basis of preparation**

These financial statements have been prepared in accordance with International Financial Reporting Standards as adopted by the European Union ("IFRS") and under the historical cost convention, as modified by the use of fair value for financial instruments measured at fair value. 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 Directors consider the going concern basis of preparation to be appropriate in preparing the financial statements.

The Group is in its development stage and has not yet moved to full commercial exploitation of its IP. During the year ended 31 December 2018 the Group recorded a loss after tax of US\$5,454,659 (2017: loss of US\$3,957,821) and a net cash outflow from operating activities of US\$4,676,346 (2017: US\$2,615,691).

On 28 December 2018 the Group raised proceeds of US\$4.0 million (excluding expenses) from investors by the issue of shares of which US\$3.7 million remain outstanding at year-end.

In considering the appropriateness of this basis of preparation, the Directors have reviewed the Group's working capital forecasts for a minimum of 12 months from the date of the approval of this financial information. Based on their consideration the Directors have reasonable expectation that the Group has adequate resources to continue for the foreseeable future and that carrying values of intangible assets are supported. Thus, they continue to adopt the going concern basis of accounting in preparing this financial information.

### 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.

### Government and other grants

Grants are not recognised until there is a reasonable assurance that the Group will comply with the conditions attaching to them and that the grants will be received. Grants are treated as deferred income and released to the income statement on the achievement of the relevant performance criteria.

### 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.

continued

## 3 Significant accounting policies continued

### Basis of consolidation

The consolidated financial statements are for the year ended 31 December 2018. They have been prepared in accordance with the requirements of International Financial Reporting Standards (IFRS) as adopted by the European Union (EU) and with those parts of the Companies Act 2006 applicable to companies reporting under IFRS

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 effected 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 provisional estimate of 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.

continued

## 3 Significant accounting policies continued

### 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 supplied 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 supplied to the customer.

The third performance obligation is the provision of preventive maintenance service. Revenue from the provision of preventive maintenance service is recognised in the period in which the services are provided over the life of the contract.

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 supplied 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 a as 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.

continued

## 3 Significant accounting policies continued

### 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 "other operating income" in the statement of comprehensive income.

### **Intangible Assets**

Patents and related rights which are acquired through a business combination, 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.

### **Provisions**

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.

continued

## 3 Significant accounting policies continued

### **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.

#### Amortised costs

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.

These assets are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. They arise principally through the provision of goods and services to customers (e.g. trade receivables), but also incorporate other types of contractual monetary asset. 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.

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.

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.

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 include:

- 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.
- Bank and other borrowings are initially recognised at fair value net of any transaction costs directly attributable to the issue of the instrument. Such interest-bearing liabilities are subsequently measured at amortised cost using the effective interest rate method, which ensures that any interest expense over the period to repayment is at a constant rate on the balance of the liability carried in the consolidated statement of financial position. For the purposes of each financial liability, interest expense includes initial transaction costs and any premium payable on redemption, as well as any interest or coupon payable while the liability is outstanding.

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.

continued

## 3 Significant accounting policies continued

### **Net finance costs**

### Finance costs

Finance costs comprise interest payable on borrowings, direct issue costs, dividends on preference shares and foreign exchange losses; and are expensed in the period in which they are incurred.

#### Finance income

Finance income comprises interest receivable on funds invested, and foreign exchange gains.

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

### Leases

Leases are classified as finance leases whenever the terms of the lease transfer substantially all the risks and rewards of ownership to the lessee. All other leases are classified as operating leases.

Leases in which a significant portion of the risks and rewards of ownership are retained by the lessor are classified as operating leases. The costs associated with operating leases are taken to the income statement on an accruals basis over the period of the lease.

### 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 arsing 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 as endorsed by the EU 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 estimates and judgements are likely to have the most significant effect on the amounts recognised in the financial statements.

## Carrying value of intangible assets

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.

continued

## 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 operates 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		
	2018	2017
	us\$	US\$
Canada	163,677	340,113
Germany	15,117	24,617
United Kingdom	38,661	111,765
United States of America	2,221,684	760,668
Total	2,439,139	1,237,163
Non-current assets		
	2018	2017
	US\$	US\$
United States of America	4,074,689	4,695,130
Total	4,074,689	4,695,130
Product and services revenue analysis  Revenue		
	2018	2017
	us\$	US\$
Polarisers	1,056,728	340,113
Parts and Upgrades	56,610	91,529
Service	117,220	154,528
Grants	1,208,581	650,993
Total	2,439,139	1,237,163

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

continued

## 5 Employees and Directors

## Staff costs for the Group and the Company during the year:

	2018	2017
	US\$	US\$
Wages and salaries	1,667,233	837,619
Social security costs	367,748	321,009
	2,034,981	1,158,628

Average monthly number of people (including directors) employed by activity:

	2018 No.	2017
		No.
Senior management including directors	9	5
R&D and clinical trial	7	7
Administration	1	1
Total	17	13

## Key management compensation:

The following table details the aggregate compensation paid to key management personnel.

	2018	2017
	US\$	US\$
Salaries and fees	873,229	512,636
Social security costs	331,771	196,462
	1,205,000	709,098

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

	2018	2017
	US\$	US\$
Depreciation		
- Owned plant and equipment	9,601	6,939
- Leased plant and equipment	539	539
Amortisation of intangible assets	616,852	361,746
Research expenses	672,633	167,655
Operating lease costs	77,971	68,335
Auditors remuneration (note 8)	42,938	143,792

## 7 Net finance expense

	2018 US\$	2017 US\$
Interest income	184	129
Total finance income	184	129
Finance expense	188,055	34,056
Total finance expense	188,055	34,056

continued

### 8 Auditor remuneration

	2018 US\$	2017
		US\$
Auditors remuneration		
Fees payable to the Group's auditor for audit of Parent Company and Consolidated Financial Statements	42,938	45,237
Fees payables to the Group's auditor for other services (assurance related services)	-	98,555

## 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:

	2018 US\$	2017 US\$
Loss for the year attributable to shareholders of the Group	(5,454,659)	(3,957,821)
Weighted average number of ordinary shares	69,940,338	28,460,390
Basic and diluted loss per share	(0.078)	(0.139)

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.

The Group sub-divided its share capital on the basis of 26.71999:1 in February 2018. The weighted average for the year ended 31 December 2017 reflects this.

## 10 Taxation

There were no charges to current corporate taxation due to the losses incurred by the Group in the period. No deferred tax assets have been recognised due to the uncertainty of reversal being dependant on future taxable profits.

Income taxes computed at the statutory federal income tax of 21% (2017: 35%) and the state income tax of 3.30% (2017: 3.30%). UK corporation tax is calculated at 19% of the estimated assessable profits for the year.

	2018 US\$	2017 US\$
Loss on ordinary activities before tax	(5,454,659)	(3,957,821)
Loss on ordinary activities multiplied by the rate of corporation tax in the US as above Effects of:	(1,145,478)	(1,385,237)
Adjustments for rate of tax in other jurisdictions	26,611	226,518
Unrelieved tax losses carried forward	1,118,867	1,158,719
Total taxation charge	-	-

The tax reform act of 1986 contains provisions which limit the ability to utilise the net operating loss carryforwards in the case of certain events including significant changes in ownership interests. If the Group's net operating loss carryforward, the Group would incur a federal income tax liability even though net operating loss carryforwards would be available in future years.

# **Notes to the Financial Statements** continued

1 Property, plant and eq	Leasehold improvements US\$	Furniture and equipment US\$	Computers and IT equipment US\$	Total US\$
Cost	<b>.</b>			·
At 1 January 2017	2,695	27,671	8,232	38,598
Additions	-	-	16,834	16,834
At 31 December 2017	2,695	27,671	25,066	55,432
Additions	-	4,952	1,599	6,551
At 31 December 2018	2,695	32,623	26,665	61,983
Accumulated depreciation				
At 1 January 2017	360	19,516	6,737	26,613
Depreciation expense	539	2,775	4,164	7,478
At 31 December 2017	899	22,291	10,901	34,091
Depreciation expense	539	3,380	6,221	10,140
At 31 December 2018	1,438	25,671	17,122	44,231
Carrying amount				
At 31 December 2017	1,796	5,380	14,165	21,341
At 31 December 2018	1,257	6,952	9,543	17,752

#### Intangible assets 12

	Patents US\$	Total US\$
Cost		
At 1 January 2017	46,000	46,000
Additions - m2m (see note 3 - basis of consolidation)	4,999,996	4,999,996
At 31 December 2017	5,045,996	5,045,996
Additions	-	-
At 31 December 2018	5,045,996	5,045,996
Accumulated amortisation		
At 1 January 2017	23,000	23,000
Amortisation expense	361,746	361,746
At 31 December 2017	384,746	384,746
Amortisation expense	616,852	616,852
At 31 December 2018	1,001,598	1,001,598
Carrying amount		
At 31 December 2017	4,661,250	4,661,250
At 31 December 2018	4,044,398	4,044,398

continued

## 13 Investment in subsidiary undertakings

	Subsidiary Undertakings
Company	US\$
Cost	
At 31 December 2017	4,342,848
Additions	-
At 31 December 2018	4,342,848
Carrying amount	
At 31 December 2017	4,342,848
At 31 December 2018	4,342,848

The Directors annually assess the carrying value of the investment in the Subsidiary and in their opinion no impairment provision is currently necessary.

The net carrying amounts noted above relates to the Subsidiary. The subsidiary undertakings during the year were as follows:

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

### 14 Trade and other receivables

	Group		Company	
Amounts falling due after one year	2018	2017	2018	2017
	US\$	US\$	US\$	US\$
Rental deposit	12,539	12,539	-	_

	Group	1	Company		
Amounts falling due within one year	2018 US\$	2017 US\$	2018 US\$	2017 US\$	
Trade receivables	166,277	750	-	-	
Other receivables	3,972,321	415,331	3,708,681	-	
Prepayments	87,367	31,686	-	-	
Due from Group undertakings	-	-	5,661,930	1,851,021	
Called up share capital not fully paid	620	620	-	-	
Due from borrowings	-	40,474	-	40,474	
	4,226,585	488,861	9,370,611	1,891,495	

The Company's other receivable of US\$3.7 million relates to the funds outstanding from the share issue on 28 December 2018.

Analysis of trade receivables based on age of invoices

	< 30	31 – 60	61 -90	> 90	Total Gross	ECL	Total Net
	£'000	£'000	£'000	£'000	£'000	£'000	£'000
2018	163,677	2,600	-	-	166,277	-	166,277
2017	750	-	-	-	750	-	750

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. Based on the analyses performed there is no material impact on the transition to ECL. The Company applies a similar approach to measuring ECL for the amounts due from group undertakings.

continued

#### Trade and other receivables continued 14

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	
	2018 US\$	2017 US\$
Component parts	651,781	649,860

#### 16 Cash and cash equivalents

•	Group		Company	
	2018	2017	2018	2017
	US\$	US\$	US\$	US\$
Cash at bank and in hand	875,601	960,217	235,766	23,106

#### 17 **Share capital**

The issued share capital of the Company was as follows:

Allotted and called up - Ordinary shares of 0.037p each	2018 No.	2018 US\$	2017 No.	2017 US\$
At beginning of period	48,470,142	23,291	2,672	1
Issue of shares on group reorganisation	-	-	42,286,709	20,320
Issue of shares to investors	47,321,448	23,540	6,180,761	2,970
Issue of shares upon converting loans	4,939,303	2,596	-	-
At end of year	100,730,893	49,427	48,470,142	23,291

The Company was incorporated on 24 October 2016 with issued share capital of £1 comprising 1 ordinary share of £1 each. On 30 May 2017 the share capital of the Group was divided into 100 ordinary shares of 1p each.

On 30 May 2017 the Company issued 1,582,587 new ordinary shares as consideration for the acquisition of 100% of the issued share capital of the Subsidiary.

On 31 May 2017, the Company raised US\$2 million of pre-IPO funding by way of the issue of 231,316 new ordinary shares at a price of £6.68 per share.

On 16 February 2018 the Company sub-divided its share capital on the basis of 26.71999:1. The number of ordinary shares in issue in the Company at 31 December 2017 reflects the sub-division.

On 28 March 2018 the Company issued 20,000,000 new ordinary shares at a price of £0.15 each.

On 16 July 2018 the Company issued 5,000,000 new ordinary shares at a price of £0.16 each.

On 28 December 2018, the Company issued 22,321,448 new ordinary shares at a price of £0.14 each. Of the US\$4.0 million (excluding expenses) raised from investors, US\$3.7 million remain outstanding at year-end.

continued

### 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.

### Other equity

Includes the value of conversion rights on convertible loans.

### 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 and cancelled/lapsed options.

### **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 2018	Weighted average exercise price (US\$) 2018	Number of share options 2017	Weighted average exercise price (US\$) 2017
Outstanding at beginning of year	5,156,960	0.02	5,156,960	0.02
Granted during the year	10,403,600	0.20	-	-
Forfeited/lapsed during the year	-	-	-	<u>-</u>
Outstanding at end of the year	15,560,560	0.13	5,156,960	0.02
Exercisable at end of the year	6,590,282	0.07	4,304,619	0.01

During the year ended 31 December 2018, 10,403,600 options were granted (2017: Nil). The options will vest in equal portions on an annual basis on the anniversary of Admission, over the four year period from the date of Admission. The options outstanding as at 31 December 2018 have an exercise price in the range of US\$0.0041 to US\$0.20 (2017: US\$0.0041 to US\$0.0337).

The fair value of options granted has been calculated using the Black Scholes model which has given rise to fair values per share of US\$0.09. This is based on risk-free rates of 1.41% and volatility of 40.84%.

The Black Scholes calculations for the options resulted in a charge of US\$211,015 (2017: US\$66,859) which has been expensed in the year.

The weighted average remaining contractual life of the share options is 7.91 years (2017: 6.2 years).

All share options are equity settled on exercise.

On 23 May 2019, the Company granted 1.2 million share options to Chuck Osborne with an exercise price of 15 pence per share. 25% of the options shall vest on 29 April 2020 with the remaining 75% vesting in equal portions on the last day of each calendar month over the period of 36 months, starting on 31 May 2020.

continued

### 19 Share based payments continued

### 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 very from agreement to agreement.

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

		Weighted		Weighted average
	Number of av share warrants 2018	erage exercise price (US\$) 2018	Number of share warrants 2017	exercise price (US\$) 2017
Outstanding at beginning of year	9,065,428	0.15	5,081,449	0.01
Granted during the year	866,236	0.20	3,983,979	0.33
Forfeited/lapsed during the year	(2,908,125)	0.30	-	-
Outstanding at end of the year	7,023,539	0.09	9,065,428	0.15
Exercisable at end of the year	7,023,539	0.09	4,371,841	0.00

On 30 May 2017, by way of a Warrant Substitution Agreement the outstanding warrants in the Subsidiary were substituted into warrants over shares in the Company. The Warrant Substitution Agreement did not vary or amend any of the terms and conditions of the warrants granted.

On completion of the m2m merger the Company granted a warrant of 5% of the issued share capital of the Subsidiary following the merger to Amphion Innovations Plc, Robert Bertoldi and Richard Morgan. A total of 2,618,373 warrants were issued pursuant to the Amphion Warrant Instrument.

On 31 May 2017 the Company granted 1,236,174 warrants to subscribers as part of the pre-merger fundraise on 31 May 2017 (Subscriber Warrants). These warrants can be exercised at any time from Admission to 25 May 2021.

As part of the pre-Admission fundraising which was completed in December 2017 the Company granted 129,432 warrants to subscribers (Pre-Admission Fundraise Warrants). These warrants can be exercised at any time from Admission to 25 May 2021.

On 11 January 2018 the Company granted 866,236 warrants to subscribers with an exercise price of 15 pence per share which vested immediately and expiry on 31 March 2019.

On 16 February 2018 the Company sub-divided its share capital on the basis of 26.71999:1. The warrants above reflect this event.

The fair value of options granted during the year have been calculated using the Black Scholes model which has given rise to fair values per share of US\$0.04. This is based on risk-free rates of 1.41% and volatility of 40.84%.

continued

## 19 Share based payments continued

The Black Scholes calculations for warrants resulted in a charge of US\$40,775 (2017: US\$348,007) which has been expensed in the year.

The weighted average remaining contractual life of the share warrants is 4.1 years (2017: 3.6 years).

On 2 April 2019 the Company issued 705,040 new ordinary shares of £0.00037 each in the capital of the Company at the exercise price of 15 pence per share, following the exercise of warrants from certain investors that subscribed in January 2018. The total consideration received by the Company pursuant to the warrant exercise will be £105,756. The remaining 157,796 warrants issued in January 2018 lapsed on 1 April 2019.

## 20 Provision for contingent consideration

	Group		Company	
	2018	2017	2018	2017
	US\$	US\$	US\$	US\$
Provision for contingent consideration	316,000	316,000	-	-

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 2018, the fair value of this contingent consideration was US\$316,000 (2017: 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 2018 necessitating revision of the probability weighted expected value of the contingent consideration.

There was therefore no profit or loss arising on revaluation of contingent consideration during the year ended 31 December 2018 (2017: nil).

## 21 Deferred income

	Group		Company	
	2018 US\$	2017 US\$	2018 US\$	2017 US\$
Arising from service contracts				
Current	54,829	26,562	-	-
Non-current	70,726	-	-	-
	125,555	26,562	-	-

## 22 Trade and other payables

	Group		Company	
	2018 US\$	2017 US\$	2018 US\$	2017 US\$
Trade payables	417,356	711,363	-	-
Accruals and other payables	923,126	945,013	28,174	25,742
Royalties	250,000	250,000	-	-
	1,590,482	1,906,376	28,174	25,742

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

Royalties comprise a fixed payment of US\$250,000 in relation to an agreement entered into by the Subsidiary for the use of patents, see note 24 – Royalty commitments.

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

23 Borrowings and loans

continued

	Group		Company	
	2018 US\$	2017 US\$	2018 US\$	2017 US\$
Related party loans	-	47,086	-	-
Overdraft	5,213	-	-	-
Note payable	-	265,750	-	-
Convertible loan notes	-	791,887	-	785,747
	5,213	1,104,723	-	785,747

In June 2013, an unsecured subordinated promissory note was issued to a related party for a principal amount of US\$8,000 per month for 18 months for a total of US\$144,000. The note bears interest at 3 per cent. per annum. All principal and outstanding interest on the note is was repaid in December 2018.

In April 2017, an unsecured loan note was issued for a principal amount of US250,000. The note bears interest at 6.75 per cent. per annum. All principal and outstanding interest on the note was repaid in April 2018.

An unsecured promissory note that was issued in June 2017 for a principal amount of US\$150,000, with an interest rate of 6 per cent per annum, was settled in full including all outstanding interest in April 2018.

In December 2017, an unsecured convertible loan note was issued for a principal amount of US\$903,000 (£647,147) was converted with accrued interest, into 4,939,303 ordinary shares in the Company at a conversion price equal to 90 per cent of the issue price of the ordinary shares upon admission.

### Net debt reconciliation

	2018 US\$	2017 US\$
Cash and cash equivalents	875,601	960,217
Current borrowings	(5,213)	(1,104,723)
Net debt	870,388	(144,506)

	Cash and cash equivalents US\$	Current borrowings US\$	Total US\$
Net debt at 1 January 2017	97,847	(104,541)	(6,694)
Cash flows Other non-cash movements	862,370 -	(1,047,014) 46,832	(184,644) 46,832
Net debt at 31 December 2017	960,217	(1,104,723)	(144,506)
Cash flows Other non-cash movements	(84,616)	307,623 791,887	223,007 791,887
Net debt at 31 December 2018	875,601	(5,213)	870,388

continued

### 24 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.

### Operating lease commitments

At 31 December 2018, the Company was committed to making the following payments under non-cancellable operating leases:

	Land & Buildings		
	2018	2017	
	US\$	US\$	
No later than one year	73,522	72,205	
Later than one year, and not later than five years	109,899	183,421	
Total	183,421	255,626	

The operating lease commitments for the rental of the property is calculated on a straight-line basis over the length of the lease.

## 25 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 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.

The Company has made unsecured interest-free loan to its Subsidiary and is repayable on demand and is expected to be repaid in the future as the Subsidiary is revenue generative.

### 25 Financial instruments continued

## Categories of financial instruments

### continued

	Group		Compa	ny
	2018 US\$	2017 US\$	2018 US\$	2017 US\$
Cash and cash equivalents	875,601	960,217	235,766	23,106
Loans and receivables				
Trade and other receivables - current	4,226,585	488,861	9,370,611	1,891,495
Trade and other receivables – non-current	12,539	12,539	-	-
Financial Liabilities measured at amortised cost				
Trade and other payables	1,590,482	1,906,376	28,174	25,742
Borrowings – current	5,213	1,104,723	-	785,747

### **Borrowings**

	Grou	р	Compa	ny
Financial Instruments	2018 US\$	2017 US\$	2018 US\$	2017 US\$
Related Party Loans	-	47,086	-	-
Overdraft	5,213	-	-	-
Note payable	-	265,750	-	-
Convertible Loan Notes	-	791,887	-	785,747
Total	5,213	1,104,723	-	785,747

In June 2013, an unsecured subordinated promissory note was issued to Technology Commercialization Group, for whom Kenneth West was a retained consultant, for a principal amount of US\$8,000 per month for 18 months for a total of US\$144,000. The note bears interest at 3 per cent. per annum. This was repaid in full in December 2018.

In December 2017, an unsecured convertible loan note was issued for a principal amount of US\$903,000 (£647,147) was converted with accrued interest, into 4,939,303 ordinary shares in the Company at a conversion price equal to 90 per cent of the issue price of the ordinary shares upon admission.

### 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 debt and equity balances. The Group is both equity and debt funded, and these two elements combine to make up the capital structure of the business. Equity comprises share capital, share premium and retained losses and is equal to the amount shown as 'Equity' in the statement of financial position. Debt comprises various items which are set out in further detail above and in note 23.

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

continued

### 25 Financial instruments continued

### (b) Market risk

The interest rate profile of the Subsidiary's borrowings is shown below:

## Interest rate profile of interest-bearing borrowings:

	2018		201	17
	Debt US\$	Interest rate	Debt US\$	Interest rate
Fixed rate borrowings Related party loans	-	-%	24,852	6-10%
Weighted average cost of fixed rate borrowings	-	-%	24,852	8%

Details of the above borrowings can be found in note 23 above.

### Interest rate sensitivity analysis

As the interest rates on shareholders loans are fixed, interest rate risk is considered to be very low.

### (c) Liquidity risk

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

	2018 US\$	2017 US\$
Less than one year	5,213	49,631
One to two years	-	-
Two to five years	-	_
Total including interest cash flows	5,213	49,631
Less: interest cash flows	-	(2,545)
Total principal cash flows	5,213	47,086

### **Derivatives**

The Group and Company have no derivative financial instruments.

### 26 Contingent liabilities

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

## 27 Related party transactions

In June 2013, an unsecured subordinated promissory note was issued to Technology Commercialization Group, for whom Ken West was a retained consultant, for a principal amount of US\$8,000 per month for 18 months for a total of US\$144,000. The note bears interest at 3 per cent per annum. All principal and outstanding interest on the note was due 3 June 2016. This was repaid in full in December 2018.

### 28 Events after the reporting period

On the 2 April 2019, the Company issued 705,040 new ordinary shares of £0.00037 each at an exercise price of 15 pence per share in relation to the warrants exercised by certain investors that subscribed for Convertible Loan Notes the Group undertook in a pre-Admission fundraise in December 2017. The Company received £105,756.

On 23 May 2019, the Company granted 1.2 million share options to Chuck Osborne with an exercise price of 15 pence per share. 25% of the options shall vest on 29 April 2020 with the remaining 75% shall vest in equal portions on the last day of each calendar month over the period of 36 months, starting on 31 May 2020.

# **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.

**NOTICE IS HEREBY GIVEN** that the second annual general meeting of Polarean Imaging plc (the 'Company') will be held at the offices of Reed Smith LLP at The Broadgate Tower, 20 Primrose Street, London EC2A 2RS at 2.00 p.m. on 25 July 2019 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:

- 1. To receive and consider the Company's audited accounts for the year ended 31 December 2018 and the directors' of the Company ("Director(s)") and auditors' reports thereon.
- 2. To consider and approve the remuneration report as detailed in the Company's annual report and accounts.
- 3. To re-appoint Crowe UK LLP as auditor of the Company (the "Auditors") 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.
- 4. To re-elect Richard Hullihen as a Director, who retires in accordance with article 78 of the Articles, and who, being eligible, offers himself for re-election.
- 5. To re-elect Bastiaan Driehuys as a Director, who retires in accordance with article 78 of the Articles, and who, being eligible, offers himself for re-election.
- 6. To re-elect Robert Bertoldi as a Director, who retires in accordance with article 78 of the Articles, and who, being eligible, offers himself for re-election.
- 7. 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 up to an aggregate number of 15,215,390 ordinary shares of £0.00037 each ("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 and 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.

# **Notice of the Annual General Meeting**

## **SPECIAL BUSINESS**

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

- 8. Subject to the passing of resolution 7 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:
  - 8.1. 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
  - 8.2. wholly for cash (otherwise than pursuant to paragraph <u>8.1</u> above) up to an aggregate number of 15,215,390 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

Registered Office:

Stephen Austin Secretary

26 June 2019

27-28 Eastcastle Street London W1W 8DH

## **Notice of the Annual General Meeting**

### **NOTES**

- (1) 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 annual general meeting. A proxy need not be a shareholder.
- (2) To appoint a proxy, shareholders should use the form of proxy enclosed with this notice of annual general meeting. 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 notarially certified copy of the same must be deposited by 2.00 p.m. (BST) on 23 July 2019 with the Company's registrars, Share Registrars Limited of The Courtyard, 17 West Street, Farnham, Surrey, GU9 7DR, United Kingdom (the 'Registrars'). The completion and return of a form of proxy does not preclude a shareholder from subsequently attending and voting at the annual general meeting in person if he or she so wishes. If a shareholder has appointed a proxy and attends the annual general meeting 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 23 July 2019 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 annual general meeting in respect of the number of ordinary shares of £0.00037 each (the 'Ordinary Shares') 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 annual general meeting.
- (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 initialed 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 5.30 p.m. Monday to Friday, excluding public holidays. Alternatively, you may write to the Registrars at Share Registrars Limited, The Courtyard, 17 West Street, Farnham, Surrey, GU9 7DR, 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 101,435,933 Ordinary Shares. Each Ordinary Share carries the right to vote at the Annual General Meeting and, therefore, the total number of voting rights in the Company as at close of business on the date immediately preceding this notice is 101,435,933.
- (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 decision. 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 notarially 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.
- (10) CREST members who wish to appoint a proxy or proxies through the CREST Electronic Proxy Appointment Service may do so for the Annual General Meeting to be held at 2.00 p.m. (BST) on 23 July 2019 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 23 July 2019, or, if the annual general meeting 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 annual general meeting 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.