

18 June 2020

Polarean Imaging Plc ("Polarean" or the "Company")

Final Results

Polarean Imaging plc (AIM: POLX), a clinical stage medical imaging technology company developing a proprietary magnetic resonance imaging (MRI) drug-device combination, announces its audited final results for the year ended 31 December 2019.

In addition, Polarean confirms that the Annual Report and Accounts for the year ended 31 December 2019, the Notice of the Annual General Meeting ("AGM") and a Form of Proxy are now available on the Company's website (<u>http://www.polarean-ir.com/content/investors/annual-reports.asp</u>) and will be posted to shareholders shortly.

Polarean's AGM will be held at 2 p.m. BST on 13 July 2020.

Highlights

- Raised £2.1 million (gross) via a placing of 11,666,667 ordinary shares at a placing price of 18p per share in July 2019
- Third trial site added at University of Cincinnati, in addition to Duke University and the University of Virginia, to improve enrolment rates for its two pivotal Phase III Clinical Trials (the "Clinical Trials")
- Completion of patient enrolment for the Clinical Trials in November 2019
- Sale and Installation of three new Polarean 9820 Xenon Polariser systems to the University of British Columbia, The Hospital for Sick Children in Toronto and the University of Iowa Hospitals and Clinics. Receipt of an order for a new Polarean 9820 Xenon Polariser system from the University of Kansas
- Third tranche of US\$1m confirmed from US\$3m Small Business Innovation Research grant
- Net cash of US\$2.0 million at 31 December 2019

Post-period end

- Positive top-line results from the Clinical Trials using hyperpolarised ¹²⁹Xenon gas, where both trials met their primary endpoint
- Raised £8.4 million (gross), including the £2.2 million subscription from new strategic investor Bracco Imaging S.p.A.
- Appointment of Jonathan Allis as Chairman
- Appointment of Cyrille Petit as Non-Executive Director
- Completion of a pre-New Drug Application meeting ("pre-NDA meeting") with the United States Food and Drug Administration ("FDA")

Richard Hullihen, CEO of Polarean, commented: "2019 has been a year of great accomplishment for Polarean. Our critical goal of executing and managing our pivotal Phase III Clinical Trials was rewarded with a successful readout in January 2020, which is a major milestone for us. Following this we raised a further £8.4 million which will enable us focus on preparing our NDA submission to the FDA in Q3 2020. We remain hopeful that this will lead to regulatory approval in H2 2021.

"We also welcome our new strategic investor, Bracco Imaging S.p.A and look forward to growing this mutually beneficial relationship. We are confident and excited for the future of Polarean and are grateful to our shareholders and stakeholders for their continued support."

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

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About Polarean (www.polarean.com)

The Company and its wholly owned subsidiary, Polarean, Inc. (together the "Group") are revenue generating, medical drug-device combination companies operating in the high resolution functional magnetic resonance imaging market.

The Group develops equipment that enables existing MRI systems to achieve an improved level of pulmonary function imaging and specialises in the use of hyperpolarised Xenon gas (¹²⁹Xe) as an imaging agent to visualise ventilation and gas exchange regionally in the smallest airways of the lungs, the tissue barrier between the lung and the bloodstream and in the pulmonary vasculature. Xenon gas exhibits solubility and signal properties that enable it to be imaged within other tissues and organs.

The Group operates in an area of significant unmet medical need and the Group's technology provides a novel diagnostic approach, offering a non-invasive and radiation-free functional imaging platform which is more accurate than current methods. The annual burden of pulmonary disease in the US is estimated to be over US\$150 billion.

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Chairman's Statement

I am excited to have become Chairman of Polarean earlier in 2020. While I have been a Board member for some time, the opportunity to assume the Chairmanship has been the best combination of timing and opportunity having just come from the sale of my former company Blue Earth Diagnostics to Bracco Imaging S.p.A. ("Bracco"). I have a direct background in the history of hyperpolarised noble gas imaging and with the founder of Polarean, it has made for an easy transition.

The critical achievements for the Company for 2019 are the successful completion of its Phase III Clinical Trials and the positive top line readout, which was subsequently announced on 29 January 2020. The Company is now moving towards the submission of its New Drug Application ("NDA") to the US Food and Drug Administration ("FDA") and simultaneously beginning the process of preparing for commercial launch. In the meanwhile, current events resulting from the COVID-19 pandemic have made clear that medicine is still not fully equipped to analyse and understand the many ways that pulmonary function can be affected by disease. Polarean has the unique ability to visualise and quantify the function of the lungs at the alveolar and capillary level. In this era of COVID-19, we believe that Polarean's technology will become increasingly important in understanding this disease and in managing post-COVID patients.

The Company looks forward to working with its growing installed base of luminary researchers to help understand the diagnosis, methods of action and therapies for all pulmonary disease.

Polarean's Directors have begun to engage with the Pharma industry. Our initial expectations of synergies and clinical trials are now in the early stages of development, leveraging our expanding installed base of top tier institutions and researchers, and we look forward to more fully exploring these potential relationships and perhaps capturing some early movers of those during 2020, based simply on the compelling ability of Polarean's technology to contribute to their processes.

Our primary focus for the coming year will be the planning and preparation for commercial launch, post anticipated FDA approval. This is an important phase in the Company's development, and we have resource coupled with some skilled service providers engaged in this effort. We look forward to the unique combination of technology and opportunity that defines the future for hyperpolarised noble gas imaging of pulmonary function.

The Company has been fortunate in its ability to attract and retain long term professional and institutional investors who I thank for their continued support. I would also like to welcome Bracco to the Company as an investor and Board member. I am aware of their specific insight into the global market for the technologies that so dramatically enhance the contributions of medical imaging equipment to medicine and patient care.

On behalf of the Board, I would like to thank the employees, stakeholders, and shareholders for their support, without which none of this would have been possible.

Jonathan Allis Non-Executive Chairman

17 June 2020

Chief Executive Officer's Statement

2019 – Year of Accomplishment of Critical Goals

The Group spent the majority of the year focused on the execution and management of its critical Phase III Clinical Trials. Once launched, discovery of key issues in enrolment required adapting and adjusting to the conditions and environments at each site versus original plans. We added a third site at the University of Cincinnati to accelerate completion of one pathway in the trial. Ultimately, we successfully completed our Trials which had a positive top line readout, and this is a major milestone towards our submission of our New Drug Application to the FDA and towards approval and commercialisation of hyperpolarised noble gas imaging for the assessment of pulmonary function.

The Opportunity

The US Healthcare system's annual burden of pulmonary disease continues unabated costing approximately US\$150 billion and your Directors still see a tremendous opportunity to bring our technology's quantitative, reproducible, non-invasive method for diagnostic and therapeutic guidance to medicine. If anything, the events of the global COVID-19 pandemic seem likely to create additional demand for managing post infection patients through extended recovery and therapeutic regimes. We have refined and extended our development of 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 maintains its intent to address the high end of the US academic and teaching hospital market segment, which comprises approximately the top 1,000 institutions nationally having multiple Centers of Excellence in Pulmonary Medicine and Radiology. The combined addressable market there for our products approaches US\$500m in equipment sales alone.

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, with its weaknesses in use for measurement of expired breath. Current imaging technologies using ionizing radiation are not widely used for assessing pulmonary function, despite their revolutionary use in other medical applications. During 2019, our additional new developments in the assessment of pulmonary vascular disease indicate early promise of the extension of our technology into Cardiology via the assessment of microvascular hemodynamics. We expanded our installed base of systems at luminary academic research centers at SickKids Hospital, Toronto, BC Children's Hospital in Vancouver, and at University of Iowa Hospitals and Clinics.

Our Organisation

The Group encountered material changes in its shareholder base during the year and as a result its Board composition and Chairmanship changed. Jonathan Allis, PhD - an existing Board member and CEO of Blue Earth Diagnostics, a PET tracer contrast agent company recently acquired by Bracco - became Chairman in February 2020. Dr. Allis, who has direct experience in hyperpolarised noble gas imaging, and whose experience in the commercialisation and launch of medical imaging contrast agents will be invaluable to Polarean in the next phases of development in submission, FDA approval, and commercialisation. In addition, following Bracco's participation in the Company's recent £8.4m fundraise (before expenses), we welcomed Mr. Cyrille Petit to the Company's Board as a Non-Executive Director and representative of Bracco. Mr. Cyrille Petit is also on the Audit Committee.

Our Operations

In 2019, we built and shipped three of our 9820 polariser systems. As we have previously explained, our production tracks the award of grants to major institutions and is historically 3-5 units per year. We see that pattern continuing and welcome the expansion of our installed base in top tier institutions. We made planned advances in our quality systems and engineering infrastructure as we move toward maturing in our new regulated environment.

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 finalised including all of the most recent developments in pulmonary vascular disease assessment and data and image analysis software. Our group has continued to push the design of the systems forward, with key advances in ease of use and manufacturability making progress in accordance with our plan. We made valuable progress on our performance and ease of use projects, which will come into play in the future.

2019 Financial results

Broadly speaking, our 2019 results are consistent with market expectations, with revenues slightly below expectations but with expenses diligently managed to also be lower than expectations. In addition, we raised US\$2.62m (before expenses) in July 2019 in a placing designed to provide additional support for the Company's Clinical Trials as patient enrolment neared completion. We benefitted from the Year 3 proceeds of the NIH SBIR Grant which we have jointly with the Cincinnati Children's Hospital Medical Center. We have maintained our pricing and margins throughout the year on equipment, albeit timing of grant receipts slightly diluted overall margins. It is still the case that the majority of our research systems are procured via grant mechanisms and while the outcomes are typically known as their process unfolds, the ultimate fiscal timing of these projects is difficult to predict with certainty as many involve public procurement cycles.

2020 and Beyond

On 4 May 2020 we had our Pre-NDA meeting with the FDA. In that meeting we discussed many items relating to our submission. We have now received the minutes of that meeting from them and confirm that the market expectation we have previously set with regard to the timing of submission and the expected times for review of the submission and Hatch Waxman request are as previously stated. We plan to file our New Drug Application with the FDA in Q3 2020 and continue to cautiously plan to receive regulatory approval twelve months after filing the NDA. In the meantime, we continue to collaborate with researchers in the US and abroad and look to expand our installed base of research systems, and have a pipeline supporting that plan. The exciting new developments in cardiology and pulmonary vascular disease are deepening, and our knowledge base about these conditions is expanding.

We are also excited by and grateful for the investment we received from Bracco in our most recent financing announced in March 2020. We welcome Bracco, who bring a wealth of direct experience in medical imaging contrast agents to the Board of Polarean and we have already benefitted from that relationship even in this short time.

The "¹²⁹Xe MRI Clinical Trials Consortium" is studying the application of our technology to the case of post infection COVID-19 patients to assess the long-term effects and case management of these patients. As this process unfolds, we will make future announcements.

We continue to explore opportunities with potential strategic partners in Pharma 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 research collaborators and research 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.

Polarean has a dedicated team of professionals without whose efforts these accomplishments would not be possible. On behalf of the entire staff of Polarean Imaging, I would like to thank our shareholders for their 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*

17 June 2020

Consolidated Statement of Comprehensive Income

		2019	2018
	Notes	US\$	US\$
Revenue	4	2,301,093	2,439,139
Cost of sales		(925,612)	(633 <i>,</i> 463)
Gross profit		1,375,481	1,805,676
Administrative expenses		(6,010,119)	(6,161,916)
Depreciation	11	(63,121)	(10,140)
Amortisation	6	(683,873)	(616,852)
Selling and distribution expenses		(324,791)	(31,766)
Share-based payment expense	19	(305,747)	(251,790)
Total administrative expenses		(7,387,651)	(7,072,464)
Operating loss	6	(6,012,170)	(5,266,788)
Finance income	7	508	184
Finance expense	7	(91,678)	(188,055)
Loss before tax		(6,103,340)	(5,454,659)
Taxation	10	-	-
Loss for the year and total other comprehensive expense		(6,103,340)	(5,454,659)
Loss per share			
Basic and diluted (US\$)	9	(0.057)	(0.078)

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

Position	Notes	2019	2018
ASSETS		US\$	US\$
Non-current assets			
Property, plant and equipment	11	355,958	17,752
Intangible assets	12	3,427,547	4,044,398
Right-of-use asset	24	98,263	-,0-+,550
Trade and other receivables	14	5,539	12,539
	14	3,887,307	4,074,689
Current assets		5,887,507	4,074,085
Inventories	15	554,211	651,781
Trade and other receivables	13	636,783	4,226,585
Cash and cash equivalents	14	1,961,869	4,220,585
	10		
		3,152,863	5,753,967
TOTAL ASSETS		7,040,170	9,828,656
Equity attributable to holders of the parent		FF 770	40 407
Share capital	17	55,776	49,427
Share premium	18	13,659,912	11,063,075
Group re-organisation reserve	18	7,813,337	7,813,337
Share-based payment reserve Accumulated losses	19	1,370,734	1,078,335
Accumulated losses	18	(18,309,681)	(12,212,767)
		4,590,078	7,791,407
Non-current liabilities			
Deferred income	21	192,817	70,726
Lease liability	24	50,455	-
Contingent consideration	20	316,000	316,000
		559,272	386,726
Current liabilities			
Trade and other payables	22	1,773,582	1,590,482
Lease liability	24	70,914	-
Borrowings	23	-	5,213
Deferred income	21	46,324	54,828
		1 000 020	
		1,890,820	1,650,523

Company Statement of Financial Position

	Notes	2019	2018
		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	11,543,854	9,370,611
Cash and cash equivalents	16	56,765	235,766
		11,600,619	9,606,377
TOTAL ASSETS		15,943,467	13,949,225
EQUITY AND LIABILITIES			
Equity attributable to holders of the particular	rent		
Share capital	17	55,776	49,427
Share premium	18	13,659,912	11,063,075
Merger reserve	18	4,322,527	4,322,527
Share-based payment reserve	19	1,065,703	773,304
Accumulated losses	18	(3,213,450)	(2,287,282)
		15,890,468	13,921,051
Current liabilities			
Trade and other payables	22	52,999	28,174
		52,999	28,174
TOTAL EQUITY AND LIABILITIES		15,943,467	13,949,225

As permitted by section 408 of the Companies Act 2006, no separate statement of Comprehensive Income is presented in respect of the parent Company. The loss for the financial year dealt with in the financial statements of the parent Company was US\$939,516 (2018: US\$1,330,568).

Consolidated Statement of Changes in Equity

	Share			Share-based	Group re-org	Accumulated	
	capital	Share premium	Other equity	payment reserve	reserve	losses	Total equity
	US\$	US\$	US\$	US\$	US\$	US\$	US\$
As at 1 January 2018	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 <i>,</i> 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
Change in accounting policy	-	-	-	-	-	(6,922)	(6,922)
Restated total equity at 1 January 2019	49,427	11,063,075	-	1,078,335	7,813,337	(12,219,689)	7,784,485
Comprehensive income							
Share based payment – lapsed share optior	-	-	-	(13,348)	-	13,348	-
Loss for the year	-	-	-	-	-	(6,103,340)	(6,103,340)
Transactions with owners							
Issue of shares	6,349	2,756,289	-	-	-	-	2,762,638
Share issue costs	-	(159,452)	-	-	-	-	(159,452)
Share-based payment expense	-	-	-	305,747	-	-	305,747
As at 31 December 2019	55,776	13,659,912	-	1,370,734	7,813,337	(18,309,681)	4,590,078

Company Statement of				Share-based payment			
Changes in Equity	Share capital	Share premium	Other equity	reserve	Merger reserve	Accumulated losses	Total equity
	US\$	US\$	US\$	US\$	US\$	US\$	US\$
As at 1 January 2018	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				251 700			251 700
expense	-	-	-	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
Comprehensive income							
Share based payment –				(13,348)		13,348	
lapsed share options	-	-	-	(13,548)	-	15,540	-
Loss for the year	-	-	-	-	-	(939,516)	(939,516)
Transactions with owners							
Issue of shares	6,349	2,756,289	-	-	-	-	2,762,638
Share issue costs	-	(159,452)	-	-	-	-	(159,452)
Share-based payment				205 747			205 747
expense	-	-	-	305,747	-	-	305,747
As at 31 December 2019	55,776	13,659,912	-	1,065,703	4,322,527	(3,213,450)	15,890,468

Consolidated Statement of Cash Flows

	Year ended 31 December 2019 US\$	Year ended 31 December 2018 US\$
Cash flows from operating activities		
Loss before tax	(6,103,340)	(5,454,659)
Adjustments for non-cash/non-operating items:		
Depreciation of plant and equipment	63,121	10,140
Amortisation of intangible assets and right-of use-asset	683,873	616,852
Share-based payment expense	305,747	251,790
Interest paid	91,678	188,055
Interest received	(508)	(184)
Operating cash flows before movements in working capital	(4,959,429)	(4,388,006)
Increase/(decrease) in inventories	97,570	(1,921)
Increase in trade and other receivables	(14,737)	(69,517)
Decrease in trade and other payables	(285,074)	(315,894)
Increase in deferred income	595,961	98,992
Net cash used in operations	(4,565,709)	(4,676,346)
Cash flows from investing activities		
Purchase of plant and equipment	(401,327)	(6,551)
Interest received	-	184
Net cash used in investing activities	(401,327)	(6,367)
Cash flows from financing activities		
Issue of shares	6,373,919	5,640,211
Cost of issue	(159,452)	(546,436)
Interest paid	-	(188,055)
Interest paid on lease liabilities	(91,678)	-
Interest received	508	5,213
Principal elements of lease payments	(69,993)	(312,836)
Net cash generated by financing activities	6,053,304	4,598,097
Net (decrease)/increase in cash and cash equivalents	1,086,268	(84,616)
Cash and cash equivalents at the beginning of year	875,601	960,217
Cash and cash equivalents at end of year	1,961,869	875,601

Company Statement of Cash Flows

	Year ended	Year ended
	31 December	31 December
	2019	2018
	US\$	US\$
Cash flows from operating activities		
Loss before tax	(939,516)	(1,330,568)
Adjustments for non-cash/non-operating items:		
Share-based payment expense	305,747	251,790
Interest received	(508)	-
Operating cash flows before movements in working capital	(634,277)	(1,078,778)
Decrease in trade and other receivables	(6,275)	-
Increase in trade and other payables	24,824	2,433
Net cash used by operations	(615,728)	(1,076,345)
Cash flows from financing activities		
Issue of shares	6,373,918	5,646,350
Cost of issue	(159,452)	(546,436)
Interest received	508	-
Loans to intercompany	(5,778,247)	(3,810,909)
Net cash generated by financing activities	436,727	1,289,005
Decrease in cash and cash equivalents	(179,001)	212,660
Cash and cash equivalents at the beginning of period	235,766	23,106
Cash and cash equivalents at end of period	56,765	235,766

Notes of the 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 16 'Leases', effective 1 January 2019

The Group has initially adopted IFRS 16 Leases from 1 January 2019. IFRS 16 introduced a single, onbalance sheet accounting model for leases. As a result, the Group, as a lessee, has recognised right-of-use assets to all existing operating leases, representing its rights to use the underlying assets and lease liabilities representing its obligation to make lease payments.

The Group has applied IFRS 16 using the modified retrospective approach, and as such, the Group is not required to present a third statement of financial position as at the date of transition. The cumulative effect of initial application is recognised in retained earnings at 1 January 2019. Accordingly, the comparative information presented for 2018 has not been restated – i.e. it is presented, as previously reported, under IAS 17 and related interpretations, with the prior period adjustments going through retained earnings, as shown within note 24.

The Group used the following practical expedients when applying IFRS 16 to leases previously classified as operating leases under IAS 17:

- Applied the exemption not to recognise right-of-use assets and liabilities for leases with less than 12 months of lease term;
- Excluded the initial direct costs from measuring the right-of-use asset at the date of initial application; and
- Used hindsight when determining the lease term if the contract contains options to extend or terminate the lease.

Standards, amendments and interpretations that are not yet effective

There are several standards, amendments to standards, and interpretations which have been issued by the IASB that are effective in future accounting periods that the group has decided not to adopt early. The most significant of these are as follows, which are all effective for the period beginning 1 January 2020:

- IAS 1 Presentation of Financial Statements and IAS 8 Accounting Policies, Changes in Accounting Estimates and Errors (Amendment Definition of Material)
- IFRS 3 Business Combinations (Amendment Definition of Business)
- Revised Conceptual Framework for Financial Reporting

• Interest Rate Benchmark Reform (IBOR) reform Phase 1 (Amendments to IFRS 9, IAS 39 and IFRS 7)

The Group is currently assessing the impact of these new accounting standards and amendments.

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 2019 the Group recorded a loss after tax of US\$6,103,340 (2018: loss of US\$5,454,659) and a net cash outflow from operating activities of US\$4,565,709 (2018: US\$4,676,346).

On 13 March 2020 the Group announced that it had conditionally raised proceeds of US\$10.4 million (excluding expenses) from investors by the issue of shares. The net proceeds of this fundraising were received shortly after the Group's General Meeting on 1 April 2020.

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.

In the current business climate, management acknowledge the COVID-19 pandemic and have implemented logistical and organisational changes to underpin the Group's resilience to COVID-19, with the key focus being protecting all personnel, minimising the impact on critical work streams and ensuring business continuity. COVID-19 may impact the Group in varying ways, which could lead to a direct bearing on the Group's ability to generate future cash flows for working capital purposes. Management are closely monitoring commercial and technical aspects of the Group's operations to mitigate the impact from the COVID-19 pandemic. The inability to gauge the length of such disruption further adds to this uncertainty. For these reasons the generation of sufficient operating cash flows remain a risk. Management believes the Group will generate sufficient working capital and cash flows to continue in operational existence and will have the ongoing support of its shareholders, if required, for the foreseeable future.

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.

Functional and presentation currency

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

3 Significant accounting policies continued

Foreign currencies

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

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

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

Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates at the dates of the initial transactions. Non-monetary items measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value is determined. The gain or loss arising on translation of non-monetary items measured at fair value is treated in line with the recognition of the gain or loss on the change in fair value of the item (i.e., translation differences on items whose fair value gain or loss is recognised in OCI or profit or loss, respectively).

Basis of consolidation

The consolidated financial statements are for the year ended 31 December 2019. 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.

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

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.

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.

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

Amortised Cost

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

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

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

Financial liabilities

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

Financial liabilities measured at amortised cost 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.

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

Definition of a lease

Previously, the Group determined at contract inception whether the arrangement was or contained a lease under IFRIC 4: Determining Whether an Arrangement contains a Lease. The Group now assesses whether a contract is or contains a lease based on the new definition of a lease. Under IFRS 16, a contract is, or contains a lease if the contract conveys a right to control the use of an identified asset for a period of time in exchange for consideration.

On transition to IFRS 16, the Group elected to apply the practical expedient to grandfather the assessment of which transactions are leases. It applied IFRS 16 only to contracts that were previously identified as leases. Contracts that were not identified as leases under IAS 17 and IFRIC 4 were not reassessed.

The Group recognises a right-of-use asset and a lease liability at the lease commencement date. The rightof-use asset is initially measured at cost, and subsequently at cost less any accumulated amortisation and impairment losses, and adjusted for certain measurements of the lease liability. Right-of-use assets are amortised on a straight-line basis over the remaining term of the lease or over the remaining economic life of the asset if, rarely, this is judged to be shorter than the lease term.

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

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

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

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.

3 Significant accounting policies continued

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.

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

	2019	2018
	US\$	US\$
Canada	897,716	163,677
Germany	-	15,117
United Kingdom	33,883	38,661
United States of America	1,369,494	2,221,684
Total	2,301,093	2,439,139
Non-current assets		
	2019	2018
	US\$	US\$
United States of America	3,887,307	4,074,689
Total	3,887,307	4,074,689

Product and services revenue analysis

Revenue

	2019	2018
	US\$	US\$
Polarisers	1,367,543	1,056,728
Parts and Upgrades	125,921	56,610
Service	55,117	117,220
Grants	752,512	1,208,581
Total	2,301,093	2,439,139

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

5 Employees and Directors

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

	2019	2018
	US\$	US\$
Wages and salaries	2,030, 730	1,667,233

Healthcare benefits	107,149	102,430
Social Security costs	122,392	94,104
	2,260,271	1,863,767

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

	2019 No.	2018 No.
Senior management including directors	11	9
R&D and clinical trial	6	7
Administration	2	1
Total	19	17

Key management compensation:

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

	2019	2018
	US\$	US\$
Salaries and fees	1,292,135	873,229
Healthcare benefits	44,597	41,909
Social security costs	69,915	49,548
	1,406,647	964,686

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

	2019 US\$	2018 US\$
Depreciation		
- Owned property, plant and equipment	63,121	9,601
 Leased property, plant and equipment 	-	539
Amortisation of right-of-use assets	67,021	-
Amortisation of intangible assets	<u>616,852</u>	<u>616,852</u>
Subtotal Amortisation	683,873	616,852
Research expenses	155,346	672,633
Operating lease costs	-	77,971
Auditors remuneration (note 8)	39,688	42,938
Clinical trial costs	1,892,592	1,781,217
Regulatory consulting costs	356.362	212.363
Legal and professional fees	348,972	111,181

7 Net finance expense

	2019	2018
	US\$	US\$
Interest income	508	184
Total finance income	508	184
Finance expense	91,678	188,055

Total finance expense	91,678	188,055
	51,078	100,000

8 Auditor remuneration

	2019 US\$	2018 US\$
Auditors remuneration		
Fees payable to the Group's auditor for audit of		
Parent Company and Consolidated Financial	39,688	42,938
Statements		

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:

	2019 US\$	2018 US\$
Loss for the year attributable to shareholders of the Weighted average number of ordinary shares	(6,103,340) 107,043,107	(5,454,659) 69,940,338
Basic and diluted loss per share	(0.057)	(0.078)

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

10 Taxation

There were no charges to 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% (2018: 21%) and the state income tax of 2.50% (2018: 3.30%) UK corporation tax is calculated at 19% of the estimated assessable profits for the year.

	2019 US\$	2018 US\$
Loss on ordinary activities before tax	(6,103,340)	(5,454,659)
Loss on ordinary activities multiplied by the rate of corporation tax in the US as above Effects of:	(1,281,701)	(1,145,478)
Adjustments for rate of tax in other jurisdictions	26,611	26,611
Unrelieved tax losses carried forward	1,255,090	1,118,867
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.

11 Property, plant and equipment

	Leasehold improvements US\$	Furniture and equipment US\$	Computers and IT equipment US\$	Total US\$
Cost				
At 1 January 2018	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
Additions	-	401,327	-	401,327
At 31 December 2019	2,695	433,950	26,665	463,310
Accumulated depreciation				
At 1 January 2018	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
Depreciation expense	539	56,438	6,144	63,121
At 31 December 2019	1,977	82,109	23,266	107,352
Carrying amount				
At 31 December 2018	1,257	6,952	9,543	17,752
At 31 December 2019	718	351,841	3,399	355,958

12 Intangible assets

	Patents US\$	Total US\$
Cost		
At 1 January 2018	5,045,996	5,045,996
Additions	-	-
At 31 December 2018	5,045,996	5,045,996
Additions	-	-
At 31 December 2019	5,045,996	5,045,996
Accumulated amortisation		
At 1 January 2018	384,746	384,746
Amortisation expense	616,852	616,852
At 31 December 2018	1,001,598	1,001,598
Amortisation expense	616,851	616,851
At 31 December 2019	1,618,449	1,618,449
Carrying amount		
At 31 December 2018	4,044,398	4,044,398
At 31 December 2019	3,427,547	3,427,547

13 Investment in subsidiary undertakings

Company	Subsidiary Undertakings US\$	
Cost		
At 31 December 2018	4,342,848	
Additions	-	
At 31 December 2019	4,342,848	
Carrying amount		
At 31 December 2018	4,342,848	
At 31 December 2019	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:

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

14 Trade and other receivables

	Group		Company	
Amounts falling due after one	2019	2018	2019	2018
year	US\$	US\$	US\$	US\$
Rental deposit	5,539	12,539	-	-

	Grou	р	Company		
	2019	2018	2019	2018	
Amounts falling due within one year	US\$	US\$	US\$	US\$	
Trade receivables	453,827	166,277	-	-	
Other receivables	97,401	3,972,321	97,402	3,708,681	
Prepayments	84,935	87,367	6,275	-	
Due from Subsidiary undertakings	-	-	11,440,177	5,661,930	
Called up share capital not fully paid	620	620	-	-	
	636,783	4,226,585	11,543,854	9,370,611	

The Company's 2018 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
2019	453,827	-	-	-	453,827	-	453,827
2018	163,677	2,600	(950)	950	166,277	-	166,277

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.

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.

The group trade receivables include governments grants amounted to US\$ 23,672 in which there are no unfulfilled conditions or contingencies attached to these grants as of 31 December 2019.

15 Inventory

	Group		
	2019 US\$	2018 US\$	
Component parts	554,211	651,781	

16 Cash and cash equivalents

	Group		Company	
	2019	2018	2019	2018
	US\$	US\$	US\$	US\$
Cash at bank and in hand	1,961,869	875,601	56,765	235,766

17 Share capital

The issued share capital of the Company was as follows:

Allotted and called up - Ordinary shares of 0.037p each	2019 No.	2019 US\$	2018 No.	2018 US\$
At beginning of period	100,730,893	49,427	48,470,142	23,291
Issue of shares upon warrant exercise	2,041,040	958	-	-
Issue of shares to investors	11,666,667	5,391	47,321,448	23,540
Issue of shares upon converting loans			4,939,303	2,596
At end of year	114,438,600	55,776	100,730,893	49,427

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.

On 2 April 2019, the Company issued 705,040 new ordinary shares upon the exercise of share warrants with an exercise price of £0.15 each.

On 22 July 2019, the Company issued 11,666,667 new ordinary shares at a price of £0.18 each.

On 24 July 2019, the Company issued 1,336,000 new ordinary shares upon the exercise of share warrants with an exercise price of £0.0003 each.

18 Reserves

Share premium

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

Group re-organisation reserve

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

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 2019	Weighted average exercise price (US\$) 2019	Number of share options 2018	Weighted average exercise price (US\$)
Outstanding at beginning of year	15,560,560	0.13	5,156,960	0.02
Granted during the year	2,610,750	0.25	10,403,600	0.20
<u>Forfeited/lapsed during the year</u>	(734,588)	0.20	-	-
Outstanding at end of the year	17,436,722	0.15	15,560,560	0.13
Exercisable at end of the year	7,366,946	0.07	6,590,282	0.07

During the year ended 31 December 2019, 2,610,750 options were granted (2018: 10,403,600). The 2019 options will vest 25% on the first anniversary of the vesting commencement date and 1/36 at the end of

every subsequent month for 36 months. The 2018 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\$0.30 (2018: US\$0.0041 to US\$0.20).

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\$305,747 (2018: US\$211,015) which has been expensed in the year.

The weighted average remaining contractual life of the share options is 7.26 years (2018: 7.91 years).

All share options are equity settled on exercise.

On 23 May 2019, the Company granted 1.2 million share options 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 2021.

On 6 November 2019, the Company granted 1,410,750 million share options with an exercise price of 23 pence per share. For 210,750 of these share options, 25% shall vest on 3 June 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 July 2021. For 1.2 million of these share options, 25% of the options shall vest on 23 October 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 30 November 2021.

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.

19 Share based payments continued

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

	Number of share warrants 2019	Weighted average exercise price (US\$)	Number of share warrants 2018	weighted average exercise price (US\$) 2018
Outstanding at beginning of year	7,023,539	0.09	9,065,428	0.15
(Exercised) / Granted during the year	(2,041,040)	0.07	866,236	0.20
Forfeited/lapsed during the year	(157,796)	0.20	(2,908,125)	0.30
Outstanding at end of the year	4,824,703	0.09	7,023,539	0.09
Exercisable at end of the year	4,824,703	0.09	7,023,539	0.09

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 2018 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%.

The Black Scholes calculations for warrants resulted in a charge of US\$40,775 for 2018 which has been expensed in that year.

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.

On 24 July 2019 the Company issued 1,336,000 new ordinary shares of £0.00037 each in the capital of the Company at the exercise price of £0.0003 per share, following the exercise of warrants. The total consideration received by the Company pursuant to the warrant exercise was £400.

The weighted average remaining contractual life of the share warrants is 3.5 years (2018: 4.1 years).

2018 US\$

20	Provision for contingent consideration	1		
		Grou	р	Company
		2019 US\$	2018 US\$	2019 US\$
	vision for contingent nsideration	316,000	316,000	-

20 Provision for contingent consideration

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 2019, the fair value of this contingent consideration was US\$316,000 (2018: 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 2019 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 2019 (2018: nil).

21 Deferred income

	Group		Company	
	2019 US\$	2018 US\$	2019 US\$	2018 US\$
Arising from service contracts				
Current	46,324	54,828	-	-
Non-current	192,817	70,726	-	-
	239,141	125,554	-	-

22 Trade and other payables

	Group		Company	
	2019 US\$	2018 US\$	2019 US\$	2018 US\$
Trade payables	660,249	417,356	14,681	-
Accruals and other payables	863,333	923,126	38,318	28,174
Royalties	250,000	250,000	-	-
	1,773,582	1,590,482	52,999	28,174

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

	Group		Company	
	2019	2018	2019	2018
	US\$	US\$	US\$	US\$
Overdraft	-	5,213	-	-
	-	5,213	-	-

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

	2019	2018
	US\$	US\$
Cash and cash equivalents	1,961,869	875,601
Current borrowings	-	(5,213)
Net debt	1,961,869	870,388

	Cash and cash equivalents US\$	Current borrowings US\$	Total US\$
Net debt at 1 January 2018	960,217	(1,104,723)	(144,506)
Cash flows	(84,616)	307,623	23,007
Other non-cash movements	-	791,887	791,887
Net debt at 31 December 2018	875,601	(5,213)	870,388
Cash flows	1,086,268	5,213	1,091,481
Other non-cash movements	-	-	-
Net debt at 31 December 2019	1,961,869	-	1,961,869

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

Transition

Previously, the Group classified property leases as operating lease under IAS 17. At transition, for leases classified as operating leases under IAS 17, lease liabilities were re-measured at the present value of the remaining lease payments, discounted at the Group's incremental borrowing rate as at 1 January 2019. Right-of-use assets are measured at their carrying value as if IFRS 16 has been applied since the commencement date, discounted using the lessee's incremental borrowing rate at the date of initial application.

Impact on transition

The impact on the statement of financial position as at 1 January 2019 as a result of adopting IFRS 16 is as follows:

	US\$
Right-of-use assets	165,284
Accumulated losses	(6,922)
Lease liability	191,361
Trade and other payables	(19,155)

When measuring lease liabilities for leases that were classified as operating leases, the Group discounted the lease payment using its incremental borrowing rate at 1 January 2019. The weighted-average rate applied is 10%.

	US\$
Operating lease commitment at 31 December 2018 as disclosed in the Group's consolidated financial statements	183,421
Plus additional lease payments	34,814
Operating lease commitment	218,235
The discounted lease liability recognised at 1 January 2019 after using the incremental borrowing rate	191,361

Impact for the period

As a of result of initially applying IFRS 16, in relation to the leases that were previously classified as operating leases, the Group recognised amortisation and interest costs, instead of operating lease expense. During the twelve months ended 31 December 2019, the Group recognised US\$67,021 of amortisation charges and US\$16,001 of interest costs from these leases.

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.

-	Group		Company	
	2019	2018	2019	2018
	US\$	US\$	US\$	US\$
Financial Assets measured at amortised cost				
Cash and cash equivalents	1,961,869	875,601	56,765	235,766
Loans and receivables				
Trade and other receivables – current	551,849	4,226,585	11,537,579	9,370,611
Trade and other receivables – non- current	5,539	12,539	-	-
Financial Liabilities measured at				
amortised cost Trade and other payables	1,773,581	1,590,482	52,998	28,17
Borrowings – current	-	5,213	-	-

Categories of financial instruments

Borrowings

Group		Company	
2019	2018	2019	2018
US\$	US\$	US\$	US\$
-	5,213	-	-
-	5,213	-	-
	2019 US\$	2019 2018 US\$ US\$ - 5,213	2019 2018 2019 US\$ US\$ US\$ - 5,213 -

25 Financial instruments continued

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 adjusts in light of changes to economic conditions and risks.

(b) Market risk

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

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:

	2019	2018
	US\$	US\$
Less than one year	1,890,820	1,650,523
One to two years	50,455	70,726
Two to five years	192,817	-
Total including interest cash flows	2,134,092	1,721,249
Less: interest cash flows	-	-
Total principal cash flows	2,134,092	1,721,249

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.

On 3 February 2020, Richard Morgan, Non-Executive Chairman and Robert Bertoldi, Non-Executive Director resigned from the Polarean Board. The unvested portion of their March 2018 stock option grants were fully vested. The exercise date for these options, 534,400 option each for Mr. Morgan and Mr. Bertoldi was extended until 31 December 2020. Jonathan Allis, Non-Executive Director, was appointed Non-Executive Chairman.

On 2 March 2020, Amphion Innovations, plc exercised 232,010 warrants at a price of £0.15 per share.

On 10 March 2020, the Subsidiary entered into a revised lease for its North Carolina offices. Under the revised terms of the lease, the Company acquired an additional 2,717 square feet of space for approximately \$52,000 per year. In addition to the expansion, the expiration date of the original lease was extended until 30 June 2022.

On 1 April 2020, the Company issued 46,624,997 new ordinary shares at a price of £0.18 each, resulting in £8.4 million gross proceeds (before expenses).

On 25 April 2020, the Subsidiary received loan proceeds in the amount of approximately US\$286,535 under the Paycheck Protection Program ("PPP"). The PPP, established as part of the Coronavirus Aid, Relief and Economic Security Act ("CARES Act"), provides for loans to qualifying businesses for amounts up to 2.5 times of the average monthly payroll expenses of the qualifying business. The loans and accrued interest are forgivable after eight weeks as long as the borrower uses the loan proceeds for eligible purposes, including payroll, benefits, rent and utilities, and maintains its payroll levels. The amount of loan forgiveness will be reduced if the borrower terminates employees or reduces salaries during the eight-week period.

The unforgiven portion of the PPP loan is payable over two years at an interest rate of 1%, with a deferral of payments for the first six months. The Subsidiary intends to use the proceeds for purposes consistent with the PPP. While the Subsidiary currently believes that its use of the loan proceeds will meet the conditions for forgiveness of the loan, we cannot assure you that we will not take actions that could cause the Subsidiary to be ineligible for forgiveness of the loan, in whole or in part

On 1 June 2020, the Company issued 534,400 new ordinary shares of £0.00037 each in the capital of the Company at the exercise price of 0.003 pence per share, following the exercise of warrants.

COVID-19

The outbreak of COVID-19 creates a new and highly unpredictable challenge. We have tested our business continuity plans which have been successfully activated.

The investment in technology over recent years has resulted in the business being well placed to continue delivering services to our clients without disruption and with no increase in operational risk.

Management do not consider it possible to quantify the true impact of COVID-19 on the business at this time but remain confident that the business can adjust to the challenges it presents.